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

| | | |
|---|---|---|
| **UNITED STATES OF AMERICA ex. rel. YOASH GOHIL,** | ) | |
| **Plaintiff/Relator,** | ) | |
| **vs.** | ) | **No. 02-cv-2964** |
| **SANOFI-AVENTIS U.S. INC.; AVENTIS, INC., AVENTIS PHARMACEUTICALS, INC., and JOHN DOES #1-50, FICTITIOUS NAMES,** | ) | |
| **Defendants.** | ) | **Plaintiff/Relator Demands Trial By Jury** |

**THIRD AMENDED QUI TAM COMPLAINT**

The Relator, Yoash Gohil, by his attorneys, Blank Rome LLP and Carl D. Poplar, P.A., files this Third Amended *Qui Tam* Complaint and, in support thereof, states as follows:

## I. THE PARTIES

### A. PLAINTIFF/RELATOR.

1. The Plaintiff/Relator Yoash Gohil was an employee of the Defendant and its predecessor companies from February 8, 1982, until he resigned in or about June 2002.

2. At all times relevant hereto, Plaintiff was a Senior Oncology Sales Representative. As a Senior Oncology Sales Specialist with Aventis, Gohil's duties included, but were not necessarily limited to, the marketing, promotion, and selling of pharmaceuticals that are manufactured and/or distributed by Defendant Aventis.

3. Aventis' Oncology Division is a separate business unit within the company.

4. Relator has direct and independent knowledge of the information on which the allegations of this lawsuit are based, and Relator voluntarily provided that information to the

Government before filing this action. Relator is an original source of the information on which the allegations of this lawsuit are based.

**B. DEFENDANTS.**

5. In 1995, Hoechst Roussel Pharmaceuticals Inc. ("HRPI") merged with Marion Merrell Dow Inc. to form the company known as Hoechst Marion Roussel Inc. ("HMR"). In 1999, Rhone-Poulenc Rorer Pharmaceuticals ("RPR") merged with HMR forming a new company known as Aventis Pharmaceuticals, Inc. Effective December 31, 2005, the operations of Aventis Pharmaceuticals, Inc. and Sanofi Syntholab, Inc. were merged into a new operating entity named Sanofi-Aventis U.S. Inc., now operating as a Delaware corporation (hereinafter referred to as "Defendant Aventis").

6. Aventis Pharmaceuticals, Inc. is the primary United States subsidiary of the Defendant Aventis, through which Defendant Aventis conducts certain of its United States operations.

7. Aventis, Inc. is a United States subsidiary and/or affiliate of the Defendant Aventis, through which Defendant Aventis conducts certain of its United States operations.

8. Defendant Aventis is a pharmaceutical company that develops, manufactures and markets numerous pharmaceutical products, which include, but are not limited to, drugs for the treatment of cancer and the side effects associated with chemotherapy. Defendant Aventis' products marketed by the Oncology Division include Taxotere and Anzemet.

9. Defendant Aventis is one of the largest and fastest growing pharmaceutical companies in the world. Defendant Aventis, a Delaware corporation, maintains a corporate headquarters and principal business address at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey.

10. At times relevant hereto, Defendant Aventis' Oncology Division employed approximately 300 oncology sales representatives, 100 sales managers and support staff managers, and 50 marketing department personnel, including product managers (hereinafter referred to as Aventis Oncology Division's "sales force"), situated and assigned throughout the United States.

11. According to figures posted on the official company website, the aforementioned affiliated entities utilizing the name and/or trading as "Aventis" collectively generated worldwide sales of 17.7 billion Euro Dollars in 2001, during the time when the herein described Fraudulent Marketing Scheme was being perpetrated.

12. John Does #1-50, fictitious names, are individuals, corporations, limited liability companies, or other lawful business entities through which Aventis does business in the United States and internationally, and who are unknown co-conspirators who conspired with Aventis to perpetuate the scheme as described herein. To the extent that any of the conduct or activities described in this Complaint were not performed by Defendant Aventis, but by the individuals described herein as John Does #1-50, fictitious names, any reference herein to Aventis under such circumstances, and only under such circumstances, refers also to John Does #1-50 and/or other co-conspirators who conspired with Aventis to perpetrate the schemes described herein.

## II. JURISDICTION AND VENUE

13. Jurisdiction is based upon 31 U.S.C. § 3732.

14. Venue is appropriate in this district under 28 U.S.C. § 3732(a), as Defendant Aventis regularly conducts business in this district and the acts complained of herein occurred in this district.

## III. AVENTIS' FRAUDULENT MARKETING SCHEME TO CAUSE FALSE CLAIMS TO BE SUBMITTED TO DEFRAUD THE GOVERNMENT

### A. THE PLAN AND PURPOSE OF THE FRAUDULENT MARKETING SCHEME.

15. It was the plan and purpose of the scheme to illegally market Taxotere between in or about 1996 and in or about January 2004 in order to fraudulently obtain Governmental reimbursement by causing false and fraudulent statements to be made, and by causing false and fraudulent claims to be submitted for payment in order to maximize Aventis' profits.

### B. THE MANNER AND MEANS OF EXECUTING THE SCHEME.

16. It was part of the scheme that Aventis illegally promoted the off-label sales and use of Taxotere in order to obtain reimbursement for non-medically accepted indications and maximize profits by making false and fraudulent statements to the public, healthcare providers and the Food and Drug Administration ("FDA").

17. It was further part of the scheme that Aventis paid illegal kickbacks in the form of sham unrestricted grants, speaking fees, travel, entertainment, sports and concert tickets, preceptorship fees, free samples, free reimbursement assistance, and other things of value to physicians, hospitals and pharmacists in order to unlawfully promote the sale and off-label use of Taxotere.

18. It was further part of the scheme that Aventis attempted to conceal and cover up the off-label marketing of Taxotere and payment of kickbacks by making false statements to the FDA and directing employees to conceal evidence.

19. The above-described scheme, described in paragraphs 15-18 is referred to herein as the "Fraudulent Marketing Scheme."

## C. THE FRAUDULENT MARKETING SCHEME TO PROMOTE TAXOTERE FOR OFF-LABEL USES.

### 1. Taxotere Is Approved By The FDA As A Cancer Treatment Only For Limited Indications.

20. Two of the pharmaceuticals manufactured and/or distributed by Defendant Aventis are Anzemet, a drug used in chemotherapy-induced nausea and vomiting and in post-operative nausea and vomiting, and Taxotere, a chemotherapeutic agent. Anzemet and Taxotere are the two products that Plaintiff Gohil was assigned to promote and sell as a sales specialist for Aventis Oncology in or about mid-1999. During the time the Fraudulent Marketing Scheme was being perpetrated, sales of Taxotere exceeded $900,000,000 in 2001, and sales of Taxotere in the United States rose 34.1% in the first quarter of 2002, totaling 151,000,000 Euro Dollars for said quarter. In 2004, net sales of Taxotere in the United States exceeded $1,400,000,000 Euro Dollars (an 11.3% increase from the prior year).

21. Taxotere is a chemotherapeutic agent that, until November 2002, was approved by the FDA for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), only after the failure of prior platinum-based chemotherapy; and in the treatment of patients with locally advanced or metastatic breast cancer, only after the failure of prior chemotherapy.

22. In November 2002, Taxotere received FDA approval for use in patients with locally advanced or metastatic non-small cell lung cancer who have not received prior chemotherapy. During the time periods relevant hereto, Taxotere had no other FDA-approved indications.

23. Taxol is a separate and distinct chemotherapeutic agent manufactured and distributed by Bristol Myers Squibb ("BMS"). Taxol has been on the market as a chemotherapeutic agent since about 1991, and is approved for use in the following settings: first-

line and subsequent therapy for the treatment of advanced carcinoma of the ovary; first-line, in combination with cisplatin, for non-small cell lung cancer; and for the adjuvant therapy of node positive breast cancer in combination chemotherapy. Taxol also has several approved uses for the second-line treatment of other cancer types.

24. Taxol was approved for generic production in about 2000. The Average Wholesale Price ("AWP") of Taxol and its generics are less than the AWP of Taxotere.

25. Between 1996 and 2004, Taxotere was the most expensive taxane on the market, selling for approximately $15,000 per treatment regimen. A substantial portion of individuals who are treated for cancer, and who are specifically treated with Taxotere and Anzemet, are participants in federal reimbursement programs.

**2. FDA Regulations Prohibit Off-Label Marketing And False And Misleading Statements About A Drug's Use.**

26. 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug. The FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. According to an FDA Final Guidance, the "legislative histories of the 1938 [Food, Drug, and Cosmetic Act] and the 1962 amendments to the act support a broad construction of what constitutes 'advertising.'" Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA further states that "thus, the agency interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

27. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. 202.1, as well as the FDA's "fair balance" requirement, described below.

28. 21 C.F.R. 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." See also 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); id. § 331(a) (prohibiting distribution of a misbranded drug); id. § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

29. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6) *et seq.* ban advertisements that are false, lacking in fair balance, or otherwise misleading.

30. 21 C.F.R. 202.1(e)(6)(iv) prohibits an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated."

31. Similarly, 21 C.F.R. 202.1(e)(6)(viii) prohibits a drug company from using "a statement by a recognized authority that is apparently favorable about a drug but fails to refer to concurrent or more recent unfavorable data or statements from the same authority on the same subject or subjects." 21 C.F.R. 202.1(e)(6)(x) states that a violation of the statute also occurs when a drug company "uses a quote or paraphrase out of context to convey a false or misleading idea."

32. 21 C.F.R. 202.1(e)(5) *et seq.* requires drug companies to present a "true statement" of information relating to the side effects, contraindications, and effectiveness of the drug use. A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications.

33. 21 C.F.R. 202.1(1)(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

34. 21 C.F.R. 201.56 requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."

35. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

36. 21 C.F.R. 99.101 *et seq.* lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

37. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. 99.101(a)(4).

38. As described below, Aventis violated these regulations by, *inter alia,* promoting the off-label use of Taxotere and advertising in a manner that did not have "fair balance," disseminating abstracts of clinical studies on off-label uses to healthcare providers that fail to meet the regulatory requirements, concealing true information about Taxotere's significant side effects, while overstating its safety and efficacy, making false and misleading statements to the public, healthcare providers and the FDA, and by disseminating communications for off-label use that were promotional in character in order to obtain federal reimbursement.

### 3. The Government Pays Claims For Taxotere Only When It Is Used To Treat A "Medically Accepted Indication" And When "Medically Necessary."

39. Pharmaceutical products that are expensive are only widely prescribed when Governmental medical expense reimbursement systems, such as Medicare, Medicaid, Champus/Tricare, and FEHBP, pay for such products.

40. Consequently, pharmaceutical manufacturers like Defendant Aventis depend upon Governmental medical expense reimbursement systems to pay for expensive pharmaceutical products sold in the United States, such as Taxotere. During the relevant time period, the AWP for Taxotere was approximately $900 for a 20 mg. dose and $1600 for 80 mg.

41. During all times relevant hereto, Defendant Aventis believed or knew these allegations to be true as a result of its experience in the pharmaceutical industry.

42. Governmentally funded medical reimbursement systems rely upon the informed, impartial and unbiased judgment of medical professionals to allocate increasingly scarce financial resources to provide necessary and appropriate care to the elderly and poor residents of the United States.

43. Pursuant to Governmental medical reimbursement systems, the Government only pays certain claims for the use of pharmaceutical drugs or biologics when a rendering healthcare provider submits a claim for reimbursement on an appropriate claim form, the claim form is completed, and the information provided on the form, if true, would make the claim eligible for reimbursement.

44. To obtain such payments, the healthcare provider must certify that the services it rendered to a patient were "medically necessary." The signature of the healthcare provider on government claim forms constitutes the provider's certification that the services rendered were "medically necessary."

45. The healthcare provider's certification that the services rendered were "medically necessary" in turn constitutes its certification that the claim is eligible for reimbursement under federal law.

46. To be eligible for reimbursement under Governmental medical reimbursement systems, a drug or biologic must be used for a "medically accepted indication."

47. A "medically accepted indication" is one that is either approved under the Food, Drug, and Cosmetic Act or listed in certain drug reporting compendia. 42 U.S.C. § 1396r-8(k)(6).

48. Congress has adopted a compendia-based system for determining appropriate Medicaid reimbursements for off-label uses of a "covered outpatient drug." Soc. Sec. Act §

1927(g)(1)(B)(i) and (k)(6) (permitting reimbursements for drug uses that "(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results"). Thus, a prescription for a particular off-label Taxotere indication must be included in one of the compendia identified in § 1927(g)(1)(B)(i) to be eligible for reimbursement under Medicaid, and other federal reimbursement programs.

49. Similarly, as stated in the 1993 Omnibus Budget Reconciliation Act (OBRA), off-label indications qualify as "medically accepted indications" for Medicare reimbursement if they are supported by a citation in an approved drug reporting compendia. 42 U.S.C. § 1395x(t)(2)(B) (Medicare); 42 U.S.C. § 1396r-8(k)(6) (Medicaid). Additionally, reimbursement under Medicare is only available to a physician if the services he or she provided were "medically required," and he or she certifies that the services performed were medically necessary. 42 U.S.C. § 1395n(a)(2).

50. Defendant Aventis promoted certain off-label indications and dosages of Taxotere, knowing they were not eligible for reimbursement because the indication or dosage was neither approved and supported on the drug reporting compendia or the relevant fiscal intermediary's Local Coverage Determination (LCD), nor was included on Taxotere's FDA-approved product labeling, and was otherwise medically unnecessary.

51. Furthermore, Defendant Aventis illegally promoted all off-label uses without meeting the FDA requirements, and without resubmitting Taxotere to the FDA testing and approval process as required by 21 U.S.C.A. § 360aaa *et seq.*

52. Thus, certain claims for reimbursement of off-label Taxotere prescriptions failed to meet the eligibility requirements of federal reimbursement programs, including, but not limited to, Medicare and Medicaid.

A. From Taxotere's initial FDA approval in 1996 through 1997, Aventis promoted Taxotere for the following treatments which, at that time, were neither approved by the FDA nor supported by the available drug compendia: (1) adjuvant breast cancer; (2) neo-adjuvant breast cancer; (3) non-small cell lung cancer (NSCLC); (4) small cell lung cancer (SCLC); (5) ovarian cancer; (6) prostate cancer; (7) head and neck cancer; (8) bladder cancer; (9) gastric cancer; (10) pancreatic cancer; (11) esophageal cancer; (12) trachea cancer; and (13) colon cancer.

B. From 1998 through 2000, Aventis promoted Taxotere for the following treatments which, at that time, were neither approved by the FDA nor supported by the available drug compendia: (1) adjuvant breast cancer; (2) neo-adjuvant breast cancer; (3) first-line ovarian cancer; (4) weekly dose for metastatic breast cancer, NSCLC, SCLC, and ovarian cancer; (5) prostate cancer; (6) head and neck cancer; (7) bladder cancer; (8) gastric cancer; (9) pancreatic cancer; (10) esophageal cancer; (11) trachea cancer; (12) colon cancer; (13) lymphoma; (14) kidney cancer; and (15) liver cancer.

C. In 2001, Aventis promoted Taxotere for the following treatments which, at that time, were neither approved by the FDA nor supported by the available drug compendia: (1) adjuvant breast cancer; (2) neo-adjuvant breast cancer; (3) first-line ovarian cancer; (4) first-line SCLC; (5) weekly dose for metastatic breast cancer, NSCLC, SCLC, ovarian cancer, head and neck cancer, and bladder cancer; (6) gastric cancer; (7) pancreatic cancer; (8) esophageal cancer; (9) trachea cancer; (10) colon cancer; (11) lymphoma; (12) kidney cancer; and (13) liver cancer. Aventis also promoted Taxotere for use as first-line treatment against NSCLC in 2001. However, in response to Aventis' 1999 supplemental new drug application (SNDA), seeking FDA approval for this indication, the FDA concluded in December 2000 that the SNDA "did not

establish the safety or effectiveness of Taxotere for the first-line treatment of NSCLC." Under 42 U.S.C. § 1395x(t)(2)(B)(ii)(I), the FDA's conclusion amounted to a determination that Taxotere was "not medically appropriate" for the first-line treatment of NSCLC. Thus, after the FDA ruling in 2000, Aventis continued to market Taxotere in violation of this FDA ruling for first-line treatment of NSCLC, which was neither FDA-approved nor a "medically accepted indication" under § 1395x(t)(2)(A).

D. From 2002 through 2004, Aventis promoted Taxotere for the following treatments which, at that time, were neither approved by the FDA nor supported by the available drug compendia: (1) adjuvant breast cancer; (2) neo-adjuvant breast cancer; (3) first-line ovarian cancer; (4) first-line SCLC; (5) weekly dose for metastatic breast cancer, NSCLC, SCLC, ovarian cancer, head and neck cancer, prostate cancer, bladder cancer, gastric cancer, and esophageal cancer; (6) trachea cancer; (7) pancreatic cancer; (8) colon cancer; (9) lymphoma; (10) kidney cancer; and (11) liver cancer. In addition, even after the FDA approved Taxotere for first-line treatment of NSCLC only *in combination with cisplatin* in November 2002, Aventis continued to market Taxotere as first-line *monotherapy* for NSCLC from 2002 to 2004. This use was neither FDA-approved, nor a "medically accepted indication" under § 1395x(t)(2)(A) from 2002 to 2004.

53. The compendia listed several forms of cancer as approved indications for Taxotere, but only with a dose of 60-100 mg per square meter of body surface area *once every three weeks*, as approved by the FDA and listed in the compendia. From 1998 to 2004, Aventis promoted Taxotere for a *weekly* dose of 40 mg per square meter of body surface area, thus increasing its reimbursements and potentially endangering patients; Taxotere may cause, *inter alia*, bone marrow suppression, anemia, fever, painful urination, blood in urine, unusual bleeding

or bruising, mouth sores and ulcers, burning, numbness, and weakness. These side effects could plausibly be exacerbated in a patient who is given a higher dose of Taxotere than the FDA-recommended amount. *See* Drug Information for the Healthcare Professional, USP DI (2004), at pp. 1162-64. *See also* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010 /020449s059lbl.pdf (listing FDA-approved dose of Taxotere and adverse reactions to drug).

54. Between 1998 and 2004, Aventis encouraged physicians to prescribe Taxotere for the first-line treatment of certain cancers, including, but not limited to ovarian and small-cell lung cancer. This promotion was in violation of regional Medicare Part B administrators' local medical necessity policies that a patient's "medical record must indicate that the patient failed previous chemotherapy" prior to the administration of Taxotere.

55. Under 42 U.S.C. § 1395x(t)(2), a non-FDA approved drug treatment must be "supported by a compendia" for the treatment to be reimbursable. Whether a particular use is "supported by" a compendium citation does not depend exclusively on whether the compendium lists the indication. Instead, support by a compendium depends on the exact use being promoted, the content of the compendium citation with respect to that exact use, and the scope and outcome of the studies as described in the compendium.

56. Between 1998 and 2004, Aventis marketed Taxotere for the treatment of certain cancers, including, but not limited to, first-line locally advanced or metastatic breast cancer, second-line NSCLC, second-line SCLC, second-line ovarian cancer, head and neck cancer, prostate cancer, bladder cancer, gastric cancer, and esophageal cancer. These indications were not "supported by" the compendia because the Taxotere studies on which the compendia relied to list accepted indications were conducted by researchers who received kickbacks from Aventis. Furthermore, these studies did not adequately address the toxicity of Taxotere, were based on

non-randomized studies, were based on preliminary and anecdotal data from studies in which not all of the treatment cycles were completed, and/or were based on phase II clinical trials. Phase II clinic trials determine if the subject drug is safe for human use and effective against the diseases in question. However, not until a drug has completed phase III trials can the compendia confirm its effectiveness, monitor its side effects, and compare it to other available treatments. *See* http://www.nlm.nih.gov/services/ctphases.html. To get indications for additional cancers listed in the compendia without the support of phase III trials, Aventis sales representatives directed physicians to whom Aventis paid kickbacks to lobby the compendia for additional listings of accepted Taxotere indications. Some of these physicians also conducted the Taxotere studies Aventis sponsored and received kickbacks from Aventis.

57. At all relevant times, Defendant Aventis knew and was aware that its Fraudulent Marketing Scheme, described above, would cause the Government, through the above-described reimbursement programs, to reimburse physicians, healthcare providers, and other purchasers of Taxotere when it was used in settings which were not eligible for reimbursement, and/or which were procured through false or fraudulent statements or through the payment of illegal kickbacks, and that this reimbursement directly resulted in profit to healthcare providers, or other purchasers of Taxotere, from the Government.

58. Furthermore, Aventis corruptly influenced the judgment of the physicians and other healthcare providers submitting those claims, records and statements, causing the submitting healthcare providers to falsely certify that certain Taxotere uses were "medically necessary," and that they had complied with all statutes, rules and regulations governing federal reimbursement, including the Federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b. But for Aventis' fraudulent promotion, healthcare providers would not have been unlawfully influenced

to prescribe certain Taxotere uses, and Medicare and Medicaid would not have otherwise reimbursed those claims.

59. Defendant Aventis therefore caused to be submitted to the Federal Government, through programs such as Medicare and Medicaid, and other federal reimbursement programs, numerous false claims and made and used false statements and records to get a false claim paid and approved.

**4. Aventis' Fraudulent Marketing Scheme Included Making False Statements To Healthcare Providers, The Public, And The FDA.**

**a. Aventis Misled The Public, Healthcare Providers, And The FDA About Taxotere.**

60. Aventis engaged in false and misleading promotion of Taxotere to the public and to healthcare providers by making false representations and omitting material facts regarding its approved indications; overstating its efficacy; concealing critical safety information; and by fraudulently promoting Taxotere for off-label uses. As a result, the Division of Drug Marketing, Advertising, and Communications (DDMAC), the marketing arm of the FDA, initiated a series of warnings to Aventis, spanning well over two years, in an effort to compel Aventis to stop these illegal promotional practices. Not only did Aventis fail to comply with DDMAC's demands, but it falsely assured DDMAC that it would cease all misleading Taxotere promotion when, in truth and fact, Aventis had been engaged in a nationwide campaign to illegally promote the off-label use of Taxotere to generate additional profits.

61. Despite Federal laws prohibiting this conduct, at all times relevant hereto, Aventis had a corporate policy to promote off-label uses of Taxotere and made false and misleading statements to the public, healthcare providers, and hospitals, falsely stating and/or implying that the drug could be used in certain settings for which it was not approved.

62. For example, as described more fully below in ¶ 67, in or about 2001, Aventis disseminated promotional brochures, misleadingly touting Taxotere's safety and efficacy for the unapproved use of first-line treatment in order to increase sales by encouraging the drug's use in a significantly larger patient population.

63. On June 30, 1999, Aventis submitted a supplemental new drug application (SNDA) to the FDA seeking approval for Taxotere in the first-line setting for non-small cell lung cancer (NSCLC), only to withdraw the application on April 26, 2000. In or about December 2000, the FDA concluded that the data in the SNDA "*did not* establish the safety or effectiveness of Taxotere for first-line treatment of NSCLC." According to the FDA, not only did the clinical trials fail to demonstrate improved survival benefits as compared to drugs that were already approved for first-line use, but, in truth and fact, the rate of deaths within 30 days and toxicity-related deaths on the Taxotere arm of the study Aventis submitted (TAX 308) was *higher* than in other randomized, controlled trials that served as the basis for the approval of other first-line treatments.

64. At the same time, Aventis trained and instructed its sales force to mislead physicians and healthcare providers by illegally promoting Taxotere and by falsely claiming Taxotere had a "better" and "more manageable safety profile" than Taxol for both NSCLC and breast cancer when, in truth and fact, Aventis knew that the FDA had specifically concluded that the available data *did not* establish Taxotere's safety or effectiveness for first-line treatment of NSCLC, nor was Taxotere approved for first-line use in either setting. Furthermore, these statements were false and fraudulent because Taxol had a *lower* incidence of severe side effects than Taxotere, as apparent from the black box warnings. Pursuant to this training, Aventis' sales

force made these false statements to healthcare providers in marketing Taxotere for off-label uses.

65. It was not until November 27, 2002 that Taxotere was approved for first-line treatment for patients with locally advanced or metastatic NSCLC, who have not already failed prior chemotherapy. Even after its approval for first-line NSCLC in late 2002, Taxotere's FDA-approval was still limited to first-line use *in combination with cisplatin.* However, as part of its Fraudulent Marketing Scheme to aggressively promote off-label uses of Taxotere, Aventis continued to fraudulently overstate Taxotere's indications in its promotional materials by disseminating sales aids suggesting it could be used as first-line *monotherapy* for NSCLC.

66. In 2001, 2002, and 2003, DDMAC sent "Untitled" and "WARNING" letters, chastising Aventis for these false and misleading claims regarding the scope of Taxotere's approved indications.

**b. Aventis Made False And Misleading Statements Regarding The Scope Of Taxotere's Treatment Usages.**

67. On July 26, 2001, DDMAC sent Aventis an untitled letter identifying promotional activities that are in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations on off-label promotion. Specifically, the FDA charged that Aventis marketed an unapproved use of Taxotere in promotional brochures distributed at a commercial exhibit booth at the 37th American Society of Clinical Oncology (ASCO) Annual Meeting held in San Francisco, California in May 2001. These brochures, which were freely available to all ASCO attendees (who were all oncology specialists), advertised Taxotere as safe and effective for first-line treatment in combination with Adriamycin, making such "conclusionary statements," such as that it was "the *only* taxane combination approved for first-line treatment of locally advanced or metastatic breast cancer." This statement was false and fraudulent because,

in truth and fact, at that time, Taxotere was not approved in combination with Adriamycin by the FDA for first-line treatment of locally advanced or metastatic breast cancer, and Aventis knew that Taxotere was only approved for *second-line* treatment of patients who had already undergone failed chemotherapy treatment. Furthermore, Aventis knew that there were *other* taxane combinations, as well as other classes of drug combinations, that *were approved* for this first-line treatment. Because Aventis had not demonstrated that Taxotere was safe and effective for any other uses, DDMAC demanded that it "should immediately cease the distribution of these and similar promotional materials."

68. At the very next annual ASCO Meeting, held in Orlando, Florida in May 2002, Aventis' illegal promotion of Taxotere again prompted DDMAC to issue another letter, demanding that Aventis cease dissemination and use of all violative promotional materials. This second letter, sent on December 18, 2002, reprimanded Aventis for using sales aids and billboards that contained false and/or misleading claims regarding Taxotere's approved indications because it used flawed study results and manipulative data presentation to imply that Taxotere was more effective than it actually was, and downplayed critical information about the severe risks and potential death that can result from Taxotere use in certain populations. Both the sales aids and billboards prominently featured queen chess pieces and proclaimed that Taxotere was "*at the center of more strategies every day.*" DDMAC condemned Aventis' overly broad advertisement as "false or misleading promotion" that "may compromise patient survival and safety."

69. Aventis responded to the December 18, 2002 letter on December 30, 2002, stating that it "wished 'to assure you [DDMAC] that effective immediately, the use of this sales aid has been discontinued' and 'all unused copies of these or similar sales aids will be destroyed.'"

Aventis further stated that "we [Aventis] are discontinuing the use of these [billboards] and any similar materials."

70. But Aventis' statements to the FDA were false and misleading in that Aventis continued its corporate policy to market Taxotere for off-label use and to use the advertisements prohibited by the FDA in 2003 and 2004.

71. Despite DDMAC's repeated demands to cease all dissemination and use of false and misleading Taxotere promotional materials, and Aventis' unambiguous assurances that it would, on July 17, 2003, DDMAC sent Aventis a letter identifying two additional promotional pieces – direct-to-consumer (DTC) ads in People Magazine from 2002 – that "raised concerns similar to those that were highlighted in the December 18, 2002 untitled letter to Aventis." In Aventis' response to DDMAC, it asserted that it believed the ads were "not inappropriate for the intended use as consumer communications," but regardless, were "not currently in use."

72. In response to the FDA, Aventis identified a third print advertisement similar to the other two cited by DDMAC, featuring a prominently placed queen chess piece underneath the slogan, "*The Next Move May Be the Key to Your Survival*," that *was* still in use. After follow up telephone calls from DDMAC to Aventis in August 2003 regarding the nature of this third advertisement, Aventis assured DDMAC in a letter dated August 21, 2003 that this third violative ad "has been discontinued and pulled from all scheduled runs."

73. The three 2003 advertisements involved the same chess theme DDMAC banned in 2002 for misleadingly suggesting that Taxotere should play a central role in cancer patients' treatment. All of the ads prominently featured a large queen chess piece and bore the slogans, *"The Next Move May Be the Key to Survival"* and/or "*It's Your Move.*"

74. Aventis' persistent disregard for DDMAC's warnings and demands to cease all fraudulent and misleading Taxotere promotion was memorialized in yet another DDMAC letter - this time, a "WARNING" letter sent on November 12, 2003. This letter details Aventis' continuing violations of the FDCA and FDA implementing regulations, describing the three DTC advertisements it circulated *even after* representing to DDMAC in December 2002 that it would discontinue the use of all fraudulent promotional materials similar to those already condemned. DDMAC points out that the DTC ads *were* substantially similar to the previously prohibited promotional materials: they involved the same chess theme and bore slogans misleadingly implying that Taxotere will result in "significant survival advantages" and implying to patients that "if they do not add Taxotere to their treatment, they **will not** survive" (emphasis in original). Because the target cancer patient audience *did* have alternative treatment options available to them with *better, proven* survival benefits than Taxotere, DDMAC concluded these ads were "misleading."

**c. Aventis Made False And Misleading Statements Regarding Taxotere's Safety And Efficacy.**

75. During the relevant time periods, Aventis overstated Taxotere's efficacy by citing flawed data, making unsupported claims, and minimizing its risks. Aventis' false and misleading sales tactics directly threatened patient safety and survival. As DDMAC warned in its December 18, 2002 letter, Aventis' use of flawed and insubstantial data and its grandiose claims of Taxotere's clinical benefits, while neglecting to mention serious risk information, could cause terminally-ill patients to receive substandard care.

76. Aventis' use of flawed data was in violation of 21 C.F.R. 202.1(e)(6)(iv), and according to DDMAC, Aventis used flawed data to conclude that Taxotere provided clinical benefits that were not demonstrated by substantial evidence or substantial clinical experience. As

DDMAC concluded in its December 18, 2002 letter, the data that Aventis claimed showed Taxotere resulted in "significant survival advantages" was actually derived from a post hoc subgroup analysis of a small patient population within a larger study, which is prohibited by 21 C.F.R. 202.1(e)(6)(v) (stating that an advertisement may not "present[] information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does"). In addition to relying on a poor study design, Aventis' promotional material further misrepresented Taxotere's efficacy by using graphs that distorted the data presentation to make it appear more favorable.

77. As recognized by DDMAC in both its December 18, 2002 letter and November 12, 2003 WARNING letter, Taxotere sales aids, billboards, and DTC advertisements deceptively claimed that the drug is "*at the center of more strategies every day.*" The sales aids also boasted "significant survival advantages" and "improved clinical benefits," when in fact, as DDMAC concluded, clinical trials actually *failed* to demonstrate improved survival benefits, the rate of deaths within 30 days and toxicity-related deaths was *higher* for Taxotere than in other randomized, controlled trials, and there is a *risk of severe adverse reactions and death* associated with Taxotere's use in specific patient populations.

78. Even after the DDMAC warnings in 2002 and 2003, Aventis continued its corporate policy to promote off-label uses of Taxotere by disseminating these misleading sales aids and brochures, as well as T-shirts and paperweights, bearing the banned slogan, "*at the center of more strategies every day*," and Aventis' sales force distributed these violative promotional items directly to physicians and other healthcare providers.

79. In addition to overstating Taxotere's benefits, Aventis also illegally concealed material information by minimizing the severe risks associated with the drug. While stretching

the truth about Taxotere's strengths, Aventis' billboards and print advertisements neglected to mention any safety or risk information contained in Taxotere's boxed warning, in violation of 21 C.F.R. 202.1(e)(6)(iv).

80. Taxotere's labeling warns of severe risks and even death in certain patient populations and provides important monitoring parameters, information regarding severe hypersensitivity reactions, and critical information regarding the drug's safe administration. The three billboards displayed at several locations during the 2002 ASCO annual meeting that DDMAC subsequently banned all featured graphics of a queen chess piece, the Taxotere product logo and website address, and two of the three included the slogan, "*at the center of more strategies every day*." None of the billboards promoting Taxotere included a brief summary or the approved product labeling. As DDMAC concluded in its December 18, 2002 letter, the temporal delay between reading the Taxotere billboard's optimistic message and learning of these serious risks was unacceptable and in violation of Federal Regulations.

81. The print DTC ads also omitted critical risk information about Taxotere, although they were disseminated months after Aventis received DDMAC warnings specifically prohibiting this omission. The ads hail Taxotere as "generally safe and tolerable," failing to present both the important information from the drug's boxed warning as well as information about its common side effects. Any risk information that was presented lacked prominence to the extent that DDMAC found it inappropriately downplayed the significant risks of using this product.

82. In a further effort to conceal its off-label promotion from the FDA, and create the false appearance that it was complying with FDA regulations, in or about October 2003, Aventis retroactively enforced sham disciplinary procedures against a sales manager that had no actual

effect on his future with the company. Despite the sales manager's claim that he was just following his supervisors' orders, Aventis issued a written warning, which had no effect on his pay or seniority, and "would in no way, shape or form have an impact upon [his] future with the company," in order to scapegoat this individual sales manager and conceal that it was, in truth and fact, its corporate policy to unlawfully promote off-label uses. In addition, Aventis advised the sales manager that it had no problem with his directing the sales force to promote off-label uses of Taxotere; the concern was merely with his specific instruction that the sales force utilize certain PowerPoint slides attached to a June 2001 e-mail in their detailing with physicians. Thus, Aventis issued these sham warnings in an attempt to conceal its off-label promotion from the FDA and create the false appearance that it had working compliance mechanisms in place.

**d. Aventis Deceived The FDA In Response To Its Repeated Warnings Regarding Its Fraudulent Promotional Activities.**

83. As described above, DDMAC repeatedly warned Aventis about its persistent and fraudulent off-label marketing and promotion of Taxotere. Although Aventis feigned remedial action in response to FDA's numerous warnings, in truth and fact, Aventis continued to lie to the FDA and withhold information regarding its specific use of violative promotional materials and the steps it took to remove them from circulation in order to conceal its Fraudulent Marketing Scheme.

84. In its December 30, 2002 response to DDMAC's WARNING letter, Aventis unambiguously stated that "we are discontinuing the use of these [billboards], *and any similar materials*." These billboards had featured queen chess pieces and two of the three misleadingly claimed that Taxotere is "*at the center of more strategies every day*," when, as DDMAC concluded, Taxotere was not central to cancer patients' treatment, and none of the billboards provided sufficient information about Taxotere's approved product labeling or boxed warning.

85. Aventis' response to DDMAC was false and fraudulent because, even after the 2002 DDMAC letter, Aventis continued its false and misleading promotional and marketing activities until at least as late as July 2003 by disseminating three DTC print advertisements that were substantially similar, and equally violative, to the billboards that triggered the 2002 warning.

86. On January 10, 2003, DDMAC demanded that Aventis compile and send a comprehensive list of "all promotional materials that contained the same or similar violations and were discontinued as a result of the untitled letter." Aventis responded on January 17, 2003 with a list of twelve items that it had "discontinued and ordered destroyed."

87. But on January 27, 2003, DDMAC was forced to contact Aventis again because its list of discontinued items had not been complete; DDMAC was particularly concerned with a "Dear Doctor" letter dated December 2002 that Aventis issued containing similar violations that should have been destroyed. DDMAC demanded that Aventis re-examine its inventory of promotional items and submit a revised list of all discontinued violative materials.

88. On February 6, 2003, Aventis sent its follow-up letter stating that it had, in fact, issued the Dear Doctor letter, but it was "intended for one-time use and has been destroyed." Aventis then admitted to one more violative promotional piece that it assured was discontinued as a result of the DDMAC warnings.

89. Yet, again, Aventis' disclosures were false, as DDMAC identified two *additional* violative DTC advertisements that Aventis had not included in either of the previous lists it submitted to DDMAC. These ads both appeared on the back of *People* magazine's circulation wrap and prominently featured Aventis' Taxotere slogans, "*The Next Move May Be the Key to Your Survival*" and "*It's Your Move*," with a picture portraying two people as pieces on a

chessboard and the queen chess piece centrally displayed between them a few squares away. DDMAC found these ads to be misleading because the headline suggests that, if cancer patients want to survive breast or lung cancer, their "next move" should include Taxotere, implying that Taxotere is "more effective than has been demonstrated by substantial evidence or substantial clinical experience." DDMAC concluded that Aventis' ads "reinforce[] the message that treatment with Taxotere will result in significant survival advantages," when, in truth and fact, the clinical data "did not necessarily represent long-term survival or a cure." DDMAC demanded that Aventis submit a letter stating the status of these items (active or discontinued) as well as yet another list of all violative promotional materials.

90. Aventis replied on August 1, 2003, assuring DDMAC that the two ads it uncovered had been discontinued and identifying another DTC piece, similar to those two ads, which falsely aggrandized Taxotere's role in patients' cancer treatment. This third ad, featuring a prominently placed queen chess piece and including the same Taxotere slogans, "*The Next Move May Be the Key to Your Survival*," and "*It's Your Move*," had been disseminated in "Coping," "MAAM," and "Cure" Magazines between March and July 2003 and was intended to be disseminated in subsequent issues of those and other publications through December 2003. Only after follow-up telephone calls did Aventis assure DDMAC in an August 21, 2003 letter that it had discontinued use of this additional misleading piece.

91. Despite repeated reprimands from DDMAC, emphasizing the importance of discontinuing all similar fraudulent promotional materials, DDMAC concluded that these later ads, like the billboards, "misleadingly overstate[d] the survival benefits . . . and impl[ied] that survival depends on treatment with Taxotere," while simultaneously "minimizing the serious and potentially life-threatening risks associated with the drug."

92. Aventis' Fraudulent Marketing Scheme did not only mislead healthcare providers and the public, but included direct deception of the FDA. The above-described false and misleading statements to the FDA were part of Aventis' larger efforts to conceal its Fraudulent Marketing Scheme to illegally promote the off-label uses of Taxotere to healthcare providers.

**e. Aventis' Fraudulent Off-Label Promotion Of Taxotere To Healthcare Providers.**

93. Despite the warnings received from DDMAC, Aventis engaged in the same fraudulent promotion to healthcare providers even after it represented to DDMAC that those promotions had ceased. In particular, despite its representations to the contrary to DDMAC, Aventis distributed banned materials to physicians and other healthcare providers until at least as late as January 2004, which promoted Taxotere by misleadingly stating it "*was at the center of more strategies every day*," and presented the same misleading brochures to physicians that overstated Taxotere's safety and efficacy that were previously prohibited by DDMAC. Aventis' sales force also disseminated product information file cards to physicians containing the same misleading slogan and substantially similar information to the previously banned brochures.

94. Aventis implemented an "official training program" wherein its sales force was required to learn all of the proper marketing, rules and regulations, and the appropriate fines, penalties, etc. under the Prescription Drug Marketing Act (PDMA). Further, Aventis provided training materials to its sales force reinforcing the proper procedures and requirements under the PDMA and the FDA guidelines. Finally, Aventis created company policies and procedures which virtually mimic the PDMA and FDA rules.

95. Despite this official training program, Aventis had an unpublished corporate policy of training its sales force to violate the rules, regulations, and requirements of the PDMA and the FDA. After members of the sales force passed the "official training program," they were

indoctrinated into the company-wide, on-the-job sales program where sales representatives were shown how to use insubstantial preliminary data in the field to induce healthcare providers to prescribe more Taxotere for on and off-label uses.

96. Once members of Aventis' sales force completed the "official training program," the company provided various "training opportunities," led by supervisory level Aventis employees who then accompany the sales representatives on various appointments, instruct and educate the sales representatives on how to use the sales data, scientific data, and various studies, including unpublished and incomplete or preliminary studies, all discussing the use of Taxotere in unapproved and non-indicated settings, to induce healthcare providers to purchase, prescribe, and use Taxotere in unapproved and non-indicated settings, and to seek reimbursement from various federal reimbursement programs, including but not limited to Medicare and Medicaid, for the use of Taxotere in non-indicated and unapproved settings.

97. Aventis' policy of using on-the-job training to teach its sales force to induce healthcare providers to prescribe, and seek reimbursement for, on and off-label uses of Taxotere from various federal reimbursement programs, including Medicare and Medicaid, by presenting insubstantial and incomplete data, and by directly misleading healthcare providers about its safety and efficacy occurred throughout the United States.

98. The official training was designed to give the appearance that Aventis is and was complying with the requirements under the PDMA when, in truth and fact, the sales and marketing techniques Aventis' sales force was required to use directly violated the PDMA and the FDA rules, and were utilized for the purpose of inducing healthcare providers to purchase Taxotere for both on and off-label uses and indications, some of which were not listed on the

drug reporting compendia, and then to seek reimbursement for which they were not eligible from the Federal Government, through such programs as Medicare and Medicaid.

99. Defendant Aventis was and is aware that the on-the-job training program in which its sales force is required to participate requires and encourages Aventis sales representatives to violate the standards put forth in the PDMA. Further, Defendant Aventis was, at all relevant times herein, and is aware that the unlawful promotion of its drugs induces and/or influences the physician and/or healthcare provider to prescribe Taxotere in non-reimbursable settings and then seek reimbursement under Medicare, Medicaid, and other federal reimbursement programs.

100. Many of the uses for which Aventis required its oncology sales force to promote Taxotere were still in the very preliminary stages of clinical research. In some instances where Taxotere was marketed to healthcare providers, there were no published studies to support the claims made by Aventis' sales representatives. In other instances, the study groups represented a very small and/or statistically insignificant group of individuals. In still other instances, Aventis required its sales representatives to ask physicians to take "a leap of faith" that Taxotere will be successful in a particular treatment area because of its purported success in a different area. All of this clinical "support" was aggressively presented and pushed on healthcare providers without the proper documentation regarding Taxotere's efficacy, toxicity, and safety.

101. Aventis made false and fraudulent statements to healthcare providers by directing its sales force to "cherry-pick" positive clinical study results and only represent the benefits, not the risks, of Taxotere in their interactions with physicians and other healthcare providers. In addition, despite the ASCO confidentiality notice that always accompanied the abstracts circulated at their annual meetings, investigators of Aventis-sponsored trials would leak preliminary results to Aventis sales managers, who would then forward the information to all

Aventis sales representatives, as well as healthcare providers, who would then begin prescribing Taxotere for off-label uses before any published data became available. Aventis would also provide PowerPoint presentations to Aventis speakers which included unbalanced preliminary data on the off-label uses of Taxotere. Approximately 80-90% of the studies Aventis used in their presentations to healthcare providers were in the form of ASCO abstracts. These abstracts are "short, preliminary summaries of research" that typically include "preliminary data" and do not "necessarily contain final results or conclusions." As such, Aventis did not present a fairly balanced picture of clinical results in their detailing with physicians in violation of 21 C.F.R. 202.1(e)(6) *et seq.*, nor did it comply with the stringent requirements for the dissemination of material on off-label drug uses set forth in 21 C.F.R. 99.101 *et seq.*

102. For example, in or about mid-2001, Aventis would instruct its sales force to discuss TAX 326 (ASCO 2001), an unpublished off-label clinical study on Taxotere use in the first-line NSCLC setting, with physicians using a mere abstract from an ASCO conference, in violation of 21 C.F.R. 99.101 *et seq*. Sales representatives were trained to highlight how this study shows there are survival advantages to using the Taxotere/Cisplatin combination over Vinorelbine/Cisplatin. However, the evidence behind this claim was merely based on preliminary data that was not statistically significant. Sales representatives also concealed the 2% toxicity-related deaths that resulted in each Taxotere arm of this study, and did not convey anything at all about Taxotere's high level of toxicity to physicians.

103. Additionally, in early 2002, when Taxol was made available in generic form at an even lower cost than Taxotere, Defendant Aventis continued to strategically and aggressively urge its sales force to downplay certain studies in order to provide false and misleading negative

and disparaging information on Taxol, and to continue to compel healthcare providers to use Taxotere in off-label settings.

104. For example, Aventis encouraged its sales force to downplay ECOG 1594 (PASCO 2000) in their conversations with physicians. This study's results emphasized the safety and efficacy of the Cisplatin/Gemcitabine and Carboplatin/Taxol combinations for the first-line treatment of NSCLC. Thus, although the study showed that Taxotere/Cisplatin actually offered *no significant difference* in the overall survival or response rate as compared to other, similar drug combinations, to strengthen its Taxotere sales pitch, Aventis trained its sales force to say that ECOG 1594 was not a properly designed study in order to conceal Taxotere's weaker safety profile from physicians.

105. Similarly, in the breast cancer setting, Aventis trained its sales force to downplay the results of CALGB 9344 and the NIH Guidelines for Adjuvant Breast Cancer, studies which showed that evidence of taxanes' role in the adjuvant treatment of node positive breast cancer was inconclusive. To market Taxotere's supposed superiority over Taxol in this setting, Aventis sales representatives were instructed to highlight mere preliminary results and abstracts from other, weaker trials, such as NSABP B-27.

106. To increase Taxotere sales, Aventis would train its sales force to emphasize the lower incidence of non-lethal side effects, such as neuropathy, that results from Taxotere usage (vs. Taxol) while not disclosing the *lethal* side effect of severe neutropenia that occurs *more frequently* with Taxotere usage. Aventis instructed its sales force to counteract various physicians' "resistance" toward certain data that was being selectively provided to them regarding the off-label use of Taxotere in adjuvant settings by using a "great letter that will highlight key points from the trial" (referring to CALGB 9344). In truth and fact, Aventis spent

$200,000 on their "Sensitivity" campaign to highlight the low incidence of neuropathy side effects to encourage healthcare providers to prescribe Taxotere when faced with a choice of taxanes, despite Taxol's lower price and lower incidence of severe side effects, thereby fraudulently increasing reimbursements from Medicare, Medicaid, and other federal reimbursement programs. Indeed, Aventis itself reported that sales of Taxotere in the United States rose 34.1% in the first quarter of 2002, while the Fraudulent Marketing Scheme was in full swing.

107. Not only did Aventis omit and conceal critical safety information by "cherry-picking" positive clinical results, it also made false statements directly to physicians in its promotion of Taxotere.

108. For example, in or about early 2001, Aventis trained its entire oncology sales force at the 2001 National Meeting to falsely represent to physicians and other healthcare providers that the Taxotere/Carboplatin combination "does not have the neuropathy, nausea/vomiting, and neutropenia" that the Taxol/Carboplatin combination did when, in truth and fact, TAX 326 and Aventis' own documents showed that Taxotere *does cause* 74% neutropenia, whereas the Taxol combination only caused 57%. Neutropenia is a blood disorder characterized by an abnormally low number of neutrophils (a type of white blood cell that serves as the body's primary defense against infections) that has the potential to be fatal.

109. In or about 2001, Aventis trained its sales force to promote the unapproved use of Taxotere for the treatment of ovarian cancer by making false and misleading statements directly to health care providers regarding the incidence of toxic deaths that resulted from Taxotere use. Although Taxotere had a higher incidence of neutropenia when compared with Taxol, the sales force was instructed to use a summary slide on the SCOTROC study in its detailing with

physicians, falsely representing that the neutropenia was "easily managed" and "not associated with an increase in treatment discontinuation or toxic deaths" when, in truth and fact, the SCOTROC study shows that neutropenic complications resulted in two septic fatalities (neutropenic complication-related deaths), as compared to one Taxol-related septic fatality.

110. Based on this training, Aventis sales representatives made these false statements directly to physicians and healthcare providers in their Taxotere promotion.

111. On e-mails and voicemails from Area Sales Trainers and Sales Managers, Aventis directed sales representatives to incorporate preliminary data on Taxotere's off-label uses in their "key selling messages" to physicians, in violation of 21 U.S.C. § 331(d), 21 C.F.R. 202.1(e)(4)(i)(a), and 21 C.F.R. 99.101(a)(2).

112. Pursuant to Aventis' national sales policy to promote off-label uses, Aventis gave its Philadelphia Area Sales Manager stacks of different studies, in various stages of completion, on off-label uses, which he then selectively provided to sales representatives for their use in detailing with healthcare providers in violation of FDA regulations and Aventis' own policies. Similarly, in a voicemail from the Scientific Information Manager to all Aventis field sales associates nationwide, she informed them that they will receive "a FedEx package containing 20-30 program brochures that have been approved for [their] distribution to physicians and nurses in [their] area that may be interested in attending a satellite symposium offering continuing education on the role of taxanes in the treatment of early state breast cancer" (an unapproved use of Taxotere).

113. Aventis' Philadelphia Area Sales Manager also selectively provided "success stories" to Aventis' sales force on the use of Taxotere in first-line NSCLC, describing a particular sales representative's success at convincing a physician to prescribe Taxotere for off-

label use, and instructed sales representatives to follow up in the positioning of Taxotere with physicians in order to get the first-line business on NSCLC and adjuvant stage breast cancer from them.

114. Defendant Aventis set specific sales goals or targets for each sales representative knowing that the improper and illegal marketing techniques will and must be used to attain the desired market share.

115. Defendant Aventis trained its sales force to stress that the "core message" its sales representatives are to convey to healthcare providers is that "Taxotere should be used for all cancer types, and in all settings." This "core message" WAS presented at all of the major sales rallies, including the National Sales Meeting.

### D. THE KICKBACK SCHEME PERPETRATED BY AVENTIS TO FURTHER ITS OFF-LABEL PROMOTION.

#### 1. Relevant Medicare And Medicaid Reporting Requirements.

116. Medicare is a federally funded health insurance program designed to provide primary health coverage for the elderly that was created in 1965 through Title XVII of the Social Security Act. In order to obtain reimbursement from the Government, each Medicare-eligible healthcare facility is required to submit, annually, a Medicare report on the Department of Health and Human Services Healthcare Financing Administration (hereafter "HCFA") Form HCFA-2552. 42 C.F.R. § 413.24(f)(iv). HCFA also sets forth detailed regulations, procedures and instructions that each Medicare program participant must follow when calculating and submitting reimbursable claims.

117. The certification contained in Form HCFA-2552, and similar forms, which certain healthcare providers who seek reimbursement must execute annually, provides in relevant part:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and

> administrative action, fines and/or imprisonment under Federal Law. Furthermore, if services identified by this report were produced through the payment directly or indirectly of a kickback or otherwise illegal criminal, civil and administrative action, fines, and/or imprisonment may result. CERTIFICATION BY OFFICER OR ADMINISTRATOR OR PROVIDER(S): I hereby certify that I have read the above statement and have examined the accompanying electronically filed or manually submitted cost report and the balance sheet and statement of revenue and expenses prepared by . . . (provider names and numbers) for the cost report beginning . . . and ending . . . To the best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with the applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of healthcare services and that the services identified in this cost report were provided in compliance with such laws and regulations.

118. The certification set forth above is contained in each Form HCFA-2552 and executed by certain healthcare providers, which were Aventis customers.

119. At all times relevant hereto, certain Medicare-eligible providers were required to sign this certification annually. Indeed, "providers of service participating in the Medicare program" are required by Soc. Sec. Act. § 1815(a) to submit to the Department of Health and Human Services information regarding the cost relating to health care services furnished to Medicare beneficiaries. Medicare regulations also state that cost reports are required from these providers on an annual basis. The HCFA-2552 certification is a prerequisite to eligibility for payment under the Medicare program. See 42 C.F.R. § 413.24(f)(4)(iv). The consequences of failure or refusal to certify as required by law and failure to report can result in all interim payments made since the beginning of the cost report being deemed overpayments. 42 U.S.C. § 1395(g); 42 C.F.R. 413.20(b) and (e).

120. Under this certification, the healthcare provider certifies that the services provided in the cost report are not infected by any kickback or any other unlawful activity. In addition,

HCFA (i) conditions both payment and provider eligibility on the veracity of the certification and the cost report; and (ii) considers invalid any cost report that contains a false statement in the certification and the amounts contained therein.

121. Aventis' customers/healthcare providers participating in Medicare are required to familiarize themselves with all applicable laws, regulations and procedures and to certify on each filed cost report that the report and any supporting documentation are true, correct and complete, and prepared from the books and records of the healthcare provider in accordance with the applicable instruction. Federal regulations also require that such providers are to furnish all information necessary to assure proper payment under the Medicare program. Concealment or silence regarding material facts affecting a healthcare provider's right to reimbursement is a violation of Federal law.

122. The Medicare and Medicaid Patient and Program Protection Act of 1987 permits the exclusion of providers who have violated the Anti-Kickback Act from future participation in Medicare and Medicaid programs. Furthermore, 42 U.S.C. 1320a-7b(a)(3) sets forth criminal penalties for failing to disclose knowledge of the occurrence of any event that would affect the initial or continued right to reimbursement under Federal healthcare programs, such as knowledge of an Anti-Kickback Act violation.

123. All providers of service participating in Medicare and Medicaid programs are required, as a condition precedent to the receipt of payment, to enter into certain "Provider Agreements" with the Government which certify that the provider will comply with all laws, regulations and program instructions concerning proper practices for providers.

124. The Provider Agreements and certifications contained therein were submitted to the Government and executed by customers who purchased goods and/or services from Aventis.

Each Provider Agreement contained a certification that the healthcare services provider would comply with all Medicare and Medicaid laws and regulations, including, but not limited to, the Anti-Kickback Act. However, certain healthcare providers who were customers of Aventis, and who received unlawful remuneration in violation of 42 U.S.C.A. § 1320a-7b(b), caused the certifications in their Provider Agreements to be false, and caused them to be in breach of their Provider Agreements.

125. Additionally, the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, requires drug manufacturers, like Aventis, to pass along any discount or rebate provided to the purchaser, including cash and volume discounts, free goods, and kickbacks, to the state, and to report "best price" information to the Centers for Medicare and Medicaid Services ("CMS"), to ensure that the Medicaid program is reimbursing for drugs at the lowest price. By not reporting the true discounts it provided to healthcare providers and other Taxotere and Anzemet purchasers, in the form of various kickbacks and free drug samples, Aventis made false statements directly to the Government by certifying its compliance with the Medicaid Rebate Statute on its quarterly reports.

126. Aventis knew that its customers must provide healthcare services in compliance with all Federal and State laws and regulations, and that compliance with such laws is a condition of payment by these programs.

### 2. Taxotere And Anzemet Were Marketed Together And Aventis Marketed The Excess Profit On Anzemet As An Inducement To Healthcare Providers To Use Taxotere.

127. In furtherance of the Fraudulent Marketing Scheme Aventis marketed Taxotere and Anzemet together, as a package.

128. Taxotere is a chemotherapy agent, the use of which often causes nausea and vomiting. Anzemet is prescribed for the treatment of post-chemotherapy nausea and vomiting.

Accordingly, when a healthcare provider purchased Taxotere as a result of Aventis' Fraudulent Marketing Scheme, Aventis intended that Anzemet would routinely be marketed to and purchased by the healthcare provider in order to address the nausea and vomiting caused by Taxotere.

129. The business plans written by Aventis addressed the promotion and sale of Taxotere and Anzemet together as a package. Similarly, Aventis' training materials and presentations discuss marketing Anzemet and Taxotere together as a package deal.

130. As part of the Fraudulent Marketing Scheme, as detailed above, Aventis marketed both Taxotere and Anzemet together as a package. In other words, when Taxotere was purchased by a healthcare provider for off-label uses because the patient needed treatment for post-chemotherapy nausea and vomiting, Aventis marketed Taxotere and Anzemet as a package deal. Thus, the same healthcare provider often purchased Anzemet when purchasing Taxotere. Aventis used the excessive profits to be realized from Anzemet purchases as a marketing device to healthcare providers to also induce the use and purchase of Taxotere.

### 3. Illegal Remuneration Was Paid To Healthcare Providers For The On And Off-Label Prescription Of Taxotere In Violation Of The Anti-Kickback Act.

131. Between in or about 1996 and January 2004, Defendant Aventis provided unlawful remuneration to physicians and other healthcare providers for speaking engagements, travel, dinners, and entertainment in violation of the Anti-Kickback Act and Aventis' own internal compliance policies. These payments are made as an inducement to the physicians and healthcare providers to prescribe Taxotere in on and off-label settings, or for high-volume uses of Taxotere.

132. Defendant Aventis would direct its sales force to recruit high-volume users of Taxotere to attend various seminars in resort hotels. The physician's travel to the seminar would

be paid for by Defendant Aventis. The hotel accommodations would be paid for Defendant Aventis. In many instances, the entertainment following the presentation was paid for by Aventis. In addition, physicians would receive "honoraria" payments from Aventis for their attendance at these seminars. Finally, in some instances, the spouse and/or children of the physician were permitted to go to the events that the physician attended, at the expense of Aventis.

133. The seminars or presentations that these leading oncologists and healthcare providers attended involved the promotion of the use of Taxotere in off-label settings. Aventis knew the purpose of these seminars is and was to encourage, induce and influence the healthcare providers to use Taxotere in these off-label settings.

134. Aventis also provided healthcare providers free tickets to various sporting events such as professional football games, professional basketball games, the NBA "All-Star Game," and U.S. Open Tennis Tournaments; to various concerts, such as the February 2002 Billy Joel/Elton John concert; tickets to the Philadelphia Orchestra; tickets to theme parks; and arranging and paying for golf outings at expensive golf courses, among other benefits furnished. In many instances, the spouse and/or children of the physician were permitted to attend said events at Aventis' expense. Defendant Aventis also provided expensive dinners at various luxury restaurants, including but not limited to "The Striped Bass," "Le Bec Fin," "Suzanna Fu's," and the "Fountain Room" in the Four Seasons Hotel in Philadelphia. These expenditures were provided to the physicians by Aventis to induce them to purchase and prescribe Taxotere and Anzemet. These tactics were part of Aventis' corporate policy and were used throughout the United States.

135. For example, in June 2001, Aventis paid Hospital A a total of $10,000 as an honorarium and grant to Physicians A, B, C, and D from the same hospital for their participation in an American Society of Clinical Oncology (ASCO) seminar. The seminar "participation" included a post-ASCO Review Golf Outing in Pittsburgh, Pennsylvania. Aventis' business from that same hospital increased over 45% in 2001.

136. In both July and August of 2001, Aventis attracted difficult-to-see oncologists to Pittsburgh Pirates baseball games to discuss prescribing Taxotere for both approved and off-label indications in breast and lung cancer settings. Aventis paid $7,500 for a luxury box for each game, in which the oncologists were hosted.

137. Additionally, Aventis recruited physicians and healthcare providers from around the country to participate in various programs sponsored by Aventis such as advisory boards, speaker training programs, and investigator meetings. Aventis created these programs for the purpose of inducing and influencing physicians and healthcare providers to use Taxotere in off-label settings and lobby the drug compendia for inclusion of additional indications for Taxotere. Aventis also persuaded the speakers who participated in these programs to promote Taxotere for off-label uses by showing them study data that favored Taxotere as an effective, safe treatment, but withholding from the speakers study data that disfavored Taxotere. Moreover, even the favorable information Aventis showed these speakers was based on non-randomized studies and preliminary and anecdotal data from studies in which not all of the treatment cycles were completed.

138. For example, throughout 2001, Group Practice A received thousands of dollars in grant money in exchange for their physicians serving as Aventis speakers on off-label uses of Taxotere at advisory boards and training workshops, nationally and internationally.

139. After Aventis provided honoraria payments, speaking fees, and grant money in excess of $250,000 to Group Practice B, not only did their Taxotere purchases increase, but a physician in the practice group who had previously been reluctant to use Taxotere in the off-label setting of adjuvant breast cancer became an Aventis speaker advocating Taxotere use in that very setting.

140. Aventis routinely considered its marketing and promotional budget for Taxotere and Anzemet in terms of the potential "return on investment."

141. For example, Aventis funded in-services, lunches, and dinners for physicians and other healthcare providers in order to unlawfully promote and induce the purchase of Taxotere. For instance, on March 7, 2001 and May 24, 2001, Aventis spent $2,500 and $3,000, respectively, on dinner programs to increase the use of Taxotere throughout the Pittsburgh region. As Aventis' Northeast Regional Manager stated with regard to these meals, "[w]e need to make sure that if we are spending money from our budget, that we are getting business in return. Return on investment must be evaluated." This was also Aventis' agenda with respect to advisory boards and speakers' training meetings: "In order to maximize the return on our investment, it is mandatory that each attendee of an advisory board or speaker's meeting be seen [by an Aventis representative] within one week of the program . . . every effort is made to identify new patients based on the data that was presented."

142. As early as 2001 and 2002, and upon information and belief, well before that time, Aventis implemented a corporate policy to provide sham unrestricted "grants" to healthcare providers for the purpose of inducing them to prescribe Taxotere in violation of the Anti-Kickback Act. Aventis engaged in the following actions, in violation of the Anti-Kickback Act, for the purpose of increasing its sales of Taxotere:

A. The Northeast Regional Sales Manager for Aventis' Oncology Department drafted business plans in 2001 and 2002 that were submitted to Aventis Oncology's upper management, including the Oncology Chief and VPs of Sales and Marketing, and were copied to the Northeast Region's entire sales force, explicitly instructing that they must "evaluate the return on investment" they are receiving from the provision of unrestricted "grants" to healthcare providers and institutions. The message of the business plan was clear and understood by Aventis' sales force: unrestricted "grants" were to be given out as an inducement to prescribe Taxotere, and decisions on the provision of unrestricted "grants" were to be made with the goal of increasing Taxotere sales. Aventis described this tactic as a "strategic imperative;"

B. Prior to approving a so-called "grant," Aventis considered "what [it] will get from supporting this program/grant" and the manner in which it could "track return of investment;"

C. Aventis gave so-called "grant" money to various healthcare providers to induce them to prescribe Taxotere, and described its corporate funding as follows: "In order to develop stronger relationships with the key academic accounts in the Northeast, we have obtained corporate funding for programs and fellowships at select institutions. These accounts influence treatment guidelines for oncologists throughout the country. In the coming year, we will need to increase our return on investment for these grants;"

D. Aventis viewed the provision of "grants" as an investment, and questioned the wisdom of providing grants to institutions that failed to subsequently increase their purchase of Taxotere. Indeed, the 2002 business plan drafted by the Eastern Regional Sales Manager for Aventis' Oncology Department stated: "We also provided corporate support to accounts such as [Group Practice C] and [Hospital B]. These investments need to be questioned and evaluated

closely moving forward. The return on investment at [Group Practice C] has not been demonstrated." Aventis also complained that "the corporate support we provided to [Hospital B] as part of a five-year commitment has not had any value in development relationships and no impact on Taxotere usage." In an inter-office memorandum dated October 29, 2000, the Eastern Regional Sales Manager for Aventis' Oncology Department stated that "We should also take a close look at accounts where we have placed significant resources and have little or no return on investment. In these accounts, we need to take a different approach;"

E. Similarly, Aventis' 2002 Regional Strategic Objectives explicitly acknowledged that money was provided as an inducement to prescribe Taxotere, recognizing that "[w]e provide a tremendous amount of both educational and financial support to the major cancer centers in the region. We have committed well over $1,000,000 in corporate support for my region in 2002. If we are not getting a significant amount of Taxotere usage from these accounts, we need to determine why." Indeed, Aventis further stated that it was "supporting a large number of programs through key academic centers in the region and [is] confident these programs will not only help reinforce recent Taxotere clinical data, but will help expand usage." Furthermore, when Aventis' Eastern Regional Sales Manager distributed Aventis' Regional Sales Update via inter-office correspondence to the East Region Sales Team, he explicitly acknowledged that "education grants" were intended to "change prescribing habits;"

F. The intent behind Aventis' provision of so-called "grants" was to increase Taxotere sales in violation of the Anti-Kickback Act;

G. The intent behind Aventis' provision of so-called "grants" to induce healthcare providers to prescribe Taxotere is further demonstrated by the fact that the

unrestricted "grant" money actually came form Aventis' "advertising and promotion" budget, rather than any sort of "education" budget.

143. In 2000, Aventis provided a $55,000 unrestricted "grant" to Hospital C. That same year, Hospital C's Taxotere sales increased by 66%.

144. Also in 2000, Aventis funded an Anzemet study at Hospital D which resulted in Anzemet being added to that hospital's formulary in November of that same year.

145. Similarly, in or about September 2000, Aventis held the Tucson Pharmacy Consultant Meeting, which Pharmacist A, a pharmacist from Hospital E, attended. At this meeting, Aventis promised a $100,000 "grant" to Pharmacist A and College A, his alma mater. One month later, on October 12, 2000, Hospital E placed Anzemet on its formulary, initiating an account worth over one million dollars.

146. In or about July 2000, Hospital E signed a performance based contract for Taxotere and Anzemet, but Hospital E did not proceed to purchase more Taxotere than it had in the past. In order to move Hospital E off of Taxol, and increase its Taxotere purchases, Aventis' Philadelphia Area Sales Manager offered a $25,000 "grant" to Group Practice D, a Hospital E practice, to switch Taxol to Taxotere in one of its physician's upcoming study, but the physician refused. In or about March 2001, when Hospital E's Taxotere sales were still lower than its Taxol purchases, Aventis arranged a corporate visit at the Ritz Carlton, Philadelphia to offer Group Practice D a total of $175,000 in grant money to facilitate a fellowship program and two clinical trials. Aventis' Philadelphia Area Sales Manager tracked Hospital E's Taxotere purchases and instructed his sales force to ensure Aventis received a return on its investment in Hospital E by influencing its physicians to prescribe more Taxotere. By in or about July 2001, when Hospital E was still not purchasing Taxotere in significant amounts, despite Aventis'

promise of "grant" money, Aventis arranged another meeting with physicians from Group Practice D in which the Area Sales Manager proposed that every time Hospital E's physicians ordered Taxol, the pharmacy should call the physician and request that he switch the order to Taxotere. Although the physicians from Group Practice D would not explicitly agree to this proposal, they responded with a commitment to increase Taxotere and Anzemet usage at Hospital E. Following this meeting, throughout the fourth quarter of 2001 and 2002, Taxotere sales at Hospital E increased. Now that it had received the return on its investment, in or about February 2002, Aventis delivered the promised $175,000 grant to Group Practice D.

147. Following a $150,000 unrestricted educational grant from Aventis on March 29, 2001, Group Practice C increased both its use of Taxotere and Anzemet, switching many patients over to off-label use of Taxotere for a variety of tumor types.

148. In 2002, Aventis gave Hospital F an unrestricted "grant" of $100,000; in July of that same year, the hospital made a $2.5 million conversion to Anzemet.

149. Aventis knew that the practices described above were illegal, and even had a corporate policy against engaging is such practices. Aventis' Policy and Procedures Manual, effective as of January 1, 2001, stated, "The giving or receiving of a grant or support of an education program may not be conditioned on an explicit or implicit agreement to purchase, prescribe, dispense, recommend, influence or provide favorable formulary status for Aventis products or in return for purchasing, prescribing..."

150. Aventis' corporate policies, however, were implemented as a subterfuge to hide the fact that it knowingly provided remuneration to healthcare providers as an inducement to increase sales of its products.

151. Despite its knowledge that its provision of so-called "grants" as an inducement to increase sales was illegal, Aventis routinely tracked the returns on its investments for both Taxotere and Anzemet from its practice of providing this unlawful remuneration to various healthcare providers and medical institutions.

**4. The "Preceptorship" Program.**

152. Defendant Aventis had a corporate policy whereby its sales representatives would and did offer physicians and healthcare providers a sum of money to observe them during the day with their patients. Aventis called this program a "preceptorship."

153. Under Aventis' official policy, a preceptorship was intended to allow the sales representative to observe the physician performing his/her duties during a one or two-hour period to learn about current medical practices and how a particular physician makes a prescribing decision. This official policy prohibits the sales representative from using the preceptorship for any promotional activity: the representative may not promote any Aventis product or view the preceptorship as an opportunity to gain access to a customer. The policy set a limit of one preceptorship per physician in a given year.

154. In reality and practice, the preceptorship program was a sham designed to disguise payments of money to gain access to physicians to promote, and influence them to prescribe, off-label uses of Taxotere, thereby increasing Taxotere sales.

155. Aventis directed its sales representatives to use preceptorships to gain access to otherwise unreachable physicians by paying them between $500 and $1000 for an hour or two of their time, despite Aventis' official policy capping the amount permitted to be paid to a physician at $500. Defendant Aventis actively and aggressively encouraged its oncology sales representatives to pursue as many preceptorship opportunities as possible, to do more than one preceptorship with the same physician annually by disingenuously requesting a preceptorship for

a different stated purpose, and to discuss and promote both the approved and off-label uses of Taxotere with the physician during the preceptorship, in direct violation of its official policy.

156. For example, on September 12, 2001, despite the official policy prohibiting discussions of drug products during the precetorship, Aventis' Philadelphia Area Trainer described using a preceptorship with a physician to successfully create the opportunity to discuss Taxotere. Specifically, the Trainer stated, "I wanted to let all of you know that I had a very successful preceptorship today with [Physician A from Group Practice E] over at [Hospital E] and . . . we just had a great day. Had the opportunity to discuss a plethora of issues surrounding Taxotere."

157. On March 1, 2001, the Philadelphia Area Sales Manager forwarded a voicemail message to his team from the Area Trainer regarding the Trainer's recent preceptorship. In the voicemail, the Sales Manager encouraged his selling team to use preceptorships to discuss Aventis products in their conversations with physicians: "I know that every clinical, every preceptorship, I did in spending clinical time with medical oncologists, I had the opportunity to discuss, yes we're there to learn, but to discuss Taxotere, the use of Taxotere, to discuss individual patients and that's what its all about (sic)."

158. Aventis used preceptorship payments to seek other returns on investment, such as the addition of one of its drugs to a hospital's formulary. For example, in 2000, Aventis arranged a preceptorship on understanding oncology practice at Hospital G and, later that same year, Anzemet was added to the hospital's formulary.

159. Defendant Aventis engaged in this "preceptorship" program throughout the entire country. The preceptorship program violates the Anti-Kickback Act because the unlawful remuneration is provided in part to influence physicians and healthcare providers to prescribe

Anzemet and Taxotere for off-label uses and thereby causes the submission of false claims for payment to the Government.

**5. Manipulation Of Dosage Amounts As A Kickback To Healthcare Providers.**

160. Defendant Aventis trained and encouraged Plaintiff, and other employees and agents, to market dosages and increased dosages and ways of using Anzemet IV with prospective and current purchasers in a manner that would increase the profit healthcare providers would obtain through reimbursement from federal programs as an inducement to purchase Taxotere. Specifically, Defendant Aventis instructed Plaintiff to encourage physicians and healthcare providers who had not previously purchased Anzemet IV to do so by promoting both the higher profit margin and the simplified dosage of 100 mg. single-use vials, a more convenient dose than that of competing products. Once physicians and healthcare providers started using Anzemet IV, Aventis' sales force was instructed to push the use of larger doses which required the purchase of two (2) vials based on a different dosage formulation.

161. For example, according to FDA guidelines, there are two approved dosages for the use of Anzemet IV in chemotherapy-induced nausea and vomiting. First, the physician may prescribe a 100 mg. fixed dose. Alternatively, a dose of 1.8 mg. per kilogram of body weight is permitted.

162. Using the second method of calculation, 1.8 mg. per kilogram of body weight, any patient weighing 56 kg (approx. 120 lbs), or more, would require more than one vial of Anzemet IV. The average patient weighs 70 kg (approx. 154 lbs). Because Defendant Aventis produced Anzemet IV only in 100 mg. single-use vials, slightly more than one vial would need to be used under the alternative dose, but the unused portion of the second vial should not be re-used. Aventis marketed this second dosage calculation to influence physicians and healthcare

providers to require two (2) vials of Anzemet IV per patient rather than the permitted one vial dose, thereby greatly increasing the number of vials and amount of Anzemet IV used, and substantially increasing the amount of profit made from reimbursement from the Government.

163. To promote the potential for this increased profit, Aventis provided two reimbursement spreadsheets showing the profit potential from purchasing two vials of Anzemet IV, as compared to the return on merely purchasing one vial, to members of its sales force to induce prospective purchasers to increase their profit margin by adopting this alternative dosing method. Aventis directed its sales force to focus the healthcare providers on the potential for increased profit, rather than the medical necessity of increased dosages, in their promotion of the alternative dosing method. Aventis' sales force engaged in this conduct throughout the country.

164. Manipulation of the dosage amount of Anzemet was a form of kickback paid to healthcare providers to induce the purchase of Taxotere, as these drugs were marketed together as a package deal.

### 6. Aventis Offers Free Samples As An Incentive To Purchase Anzemet And To Induce The Purchase Of Taxotere.

165. Defendant Aventis has trained and encouraged Plaintiff and others in its sales force to distribute many free samples of Anzemet IV, not only to prospective purchasers, but to current purchasers of this drug. Thus, even though certain physicians, healthcare providers and purchasers of Anzemet IV already contracted for certain amounts of Anzemet IV, Defendant Aventis continued to provide them free samples.

166. On various occasions, when a physician indicated difficulty in obtaining reimbursement for Taxotere, Aventis would provide free samples of Anzemet to placate the physicians.

167. Aventis was aware that, by providing free samples as compensation for the denial or delay of Taxotere reimbursements, Aventis intended that the healthcare providers would be billing for the free samples.

168. As part of its scheme to provide large numbers of free samples to healthcare providers to induce the purchase of Taxotere, Defendant Aventis violated the sample inventory and reporting requirements of the PDMA, specifically, 21 U.S.C.A. § 353(d), *et. seq.*

169. For example, the Philadelphia Area Sales Manager directed his sales force to count the drug samples in their possession, write down the inventory numbers for each kind of drug, and then forward those numbers directly to him for input into the inventory/audit system, despite the fact that he had never physically inspected the location where the drug samples were stored, nor personally verified the inventory numbers provided by the sales representatives. Another time, the Area Sales Manager broadcast his code number via voicemail to the sales representatives in his territory, directing them to input the inventory data into the computerized inventory/auditing system under his code number, without his ever physically inspecting the location where the drug samples were stored and without verifying the inventory count.

170. In or about January 2003, Aventis retroactively enforced sham disciplinary procedures against its Philadelphia Area Sales Manager for three years of violating the sample inventory and audit reporting requirements. Aventis issued him a "Final Written Warning" that had no actual effect on his pay or seniority.

171. Aventis' sales force engaged in this practice while also promoting the profitability of Anzemet IV, in conjunction with Taxotere, to healthcare providers.

172. Aventis' sales force engaged in this practice while also providing assistance concerning how to fill out claim forms to be submitted to the Government in connection with the purchase of Anzemet IV and Taxotere.

173. The improper emphasis by Aventis' sales force on the potential for substantial profit by the healthcare providers coupled with the distribution of free samples of Anzemet IV to existing purchasers of this product violates the Federal Anti-Kickback Act and the False Claims Act.

**7. Aventis' Reimbursement Assistance Scheme.**

174. Defendant Aventis has also engaged in providing free "value-added" services to physicians and healthcare providers through the Providing Access to Cancer Therapy (PACT) Program to assist them in obtaining reimbursement for unlisted off-label uses from the Government, through such programs as Medicare, Medicaid, and other federal reimbursement programs.

175. Under this scheme, Defendant Aventis knew and knows that the physicians who are prescribing Taxotere in unapproved settings that are not listed on the drug reporting compendia or approved by the fiscal intermediary would encounter difficulty in receiving reimbursement from the Government for the cost of the drug. Thus, Defendant Aventis implemented a plan to provide free assistance to physicians and healthcare providers to obtain reimbursement from Medicare, Medicaid, and other federal reimbursement programs.

176. Initially, the physician and/or healthcare provider purchases Taxotere from Aventis. After the physician/healthcare provider has used Taxotere for a patient, it is billed to Medicare or Medicaid, and other federal reimbursement programs, in the normal course of business. If the drug was used for an unlisted off-label use, and/or lacked the required medical documentation, Medicare, Medicaid, and other federal reimbursement programs would often

reject the payment. Thus, Aventis developed a toll-free reimbursement hotline to assist the physician with this collection.

177. The PACT specialists at the free reimbursement hotline service provide such free assistance to healthcare providers on matters such as coverage, fees, coding, claims submission, documentation support, letters of medical need, and obtaining reimbursement information from specific insurers, such as Medicare, Medicaid and many commercial insurers.

178. If, after contacting the free PACT hotline, the physician or healthcare provider continues to have the claim denied, the physician will receive additional free assistance from Aventis' reimbursement department. At times, Aventis' reimbursement department actually took over the collection of the claim to get it reimbursed through Medicare, Medicaid, and other federal reimbursement programs.

179. Defendant Aventis provides these free reimbursement services to physicians and healthcare providers as an incentive and/or inducement to purchase and use Taxotere in unapproved, non-reimbursable settings.

180. Defendant Aventis knew that certain unlisted off-label uses of Taxotere, which it unlawfully promoted, are not eligible to be reimbursed under Medicare, Medicaid, and other federal reimbursement programs. However, by providing the free reimbursement services, Defendant Aventis in effect works for the physician to get Taxotere approved for reimbursement under these federal programs.

### 8. Aventis Utilizes Third-Party Contractors To Pay Kickbacks To Conceal Its Off-Label Promotional Activity

181. Dating back to at least 1996, RPR, Aventis' predecessor in interest, used third-party contractors, Co-Med Communications, Inc. and Genecom, to conceal its off-label promotional activity and launder payments to promote off-label marketing.

182. Aventis/RPR provided funds to third-party contractors such as Co-Med and Genecom, who would then turn around and enter into agreements with physicians and group practices and use the funds provided by Aventis/RPR as kickbacks to the physicians and group practices. Aventis/RPR attempted to insulate itself from any liability associated with its off-label marketing because it was not directly providing the kickbacks or entering into agreements with the physicians and group practices regarding off-label promotional activity.

183. An internal document outlined the use of services being provided by Co-Med:

> "Speaker Programs: "Taxotere and Gliadel physician programs (on ***and off label*) *are processed through Co-Med***. Co-Med is responsible for securing contracts with speakers…"
>
> Preceptorship Agreements: …can be through individual physicians or with an institution…
>
> Grant Agreements: …agreement for support of educational/scientific activities…"

184. The utilization of Co-Med was no small endeavor as RPR budgeted nearly $500,000 in fiscal year 1996 for speaker programs via Co-Med.

185. RPR likewise acknowledged the use of Genecom for its off-label promotional activity:

> ***Genecom*** (a division of Robert Becker Agency) ***is the administrator of grants for "off-label" events***. "Off-label" means the event is promoting an indication that has not yet been approved by the FDA and is therefore not on our labeling. RPR cannot legally promote that indication. The contract stipulates that RPR is not influencing the speaker…."
>
> Colleen will send us a sample report that Genecom generates….

186. RPR directed that if a physician was going to speak and promote Taxotere for an off-label use, that physician had to sign a Genecom (as opposed to an RPR) speaking form.

187. These practices continued after Aventis was formed in 1999. In addition, between 1999 and 2004, Aventis continued to perpetrate this concealment of its off-label marketing scheme through another third-party contractor, Pharmedica Communications.

## IV. AVENTIS' FRAUDULENT MARKETING SCHEME VIOLATED THE FALSE CLAIMS ACT

### A. DEFENDANT KNEW AND INTENDED THAT ITS FRAUDULENT MARKETING SCHEME WOULD RESULT IN THE SUBMISSION OF INELIGIBLE AND FALSE CLAIMS FOR REIMBURSEMENT TO THE GOVERNMENT.

188. Because Aventis unlawfully promoted on and off-label Taxotere uses by presenting preliminary data, by making false and misleading statements regarding Taxotere's safety and efficacy to the public, healthcare providers, and the FDA, and by the payment of unlawful kickbacks to healthcare providers, it corruptly influenced those healthcare providers' professional medical judgment. As a direct result of Aventis' Fraudulent Marketing Scheme, healthcare providers prescribed Taxotere for indications that were not "medically necessary;" were not otherwise eligible for reimbursement; and/or were unlawfully induced by payment of kickbacks.

189. During the time that the Fraudulent Marketing Scheme was being perpetrated, Defendant Aventis knew that the FDA had only approved Taxotere for certain limited indications. Defendant Aventis further knew that certain Taxotere uses it promoted were not "medically necessary," and certain indications were not "medically accepted indications," because they were neither included on the FDA-approved product labeling nor were they listed on the relevant drug reporting compendia or approved for reimbursement by the relevant fiscal intermediary.

190. During all times relevant to this Complaint, Defendant knew that Taxotere treatments would only be widely prescribed for on and off-label treatments if Governmental

medical reimbursement systems reimbursed claims for Taxotere prescriptions, due to the high cost of these treatments.

191. Thus, during the time that the Fraudulent Marketing Scheme was being perpetrated, Defendant Aventis knew and intended that the Fraudulent Marketing Scheme would result in the submission of false claims for reimbursement, pursuant to Governmental medical reimbursement systems, for both on-label uses and off-label uses of Taxotere.

### B. AVENTIS' FRAUDULENT MARKETING SCHEME IN FACT CAUSED THE SUBMISSION OF FALSE AND INELIGIBLE CLAIMS FOR REIMBURSEMENT TO THE GOVERNMENT.

192. Annual U.S. sales exceeding one billion dollars for an expensive drug or biologic like Taxotere can occur only if a Governmental medical reimbursement system such as Medicare or Medicaid reimburses claims for widespread use of the drug.

193. Over the four-year period between 2000 and 2004, Defendant Aventis' annual sales of Taxotere increased from $424 million to approximately $1.4 billion.

194. Because of the limited approved uses of Taxotere, and as a direct result of Aventis' Fraudulent Marketing Scheme to promote Taxotere for off-label uses, by in or about 2001, Aventis achieved approximately 90% of its Taxotere sales for off-label uses.

195. Due to the high cost of Taxotere, the substantial volume of Taxotere sales could occur only if a Governmental medical reimbursement system reimbursed large numbers of claims for those Taxotere prescriptions.

196. Defendant Aventis' Fraudulent Marketing Scheme caused healthcare providers to prescribe Taxotere for both on and off-label treatments of cancer who would not have otherwise done so, but for Defendant's Fraudulent Marketing Scheme.

197. Consequently, Defendant Aventis' Fraudulent Marketing Scheme caused a substantial number of healthcare providers to submit claims for reimbursement to Governmental

medical reimbursement systems for the use of Taxotere, which would not have otherwise been paid had the Government reimbursement programs known of Aventis' Fraudulent Marketing Scheme.

### C. CLAIMS FOR PAYMENT FOR TAXOTERE DURING RELEVANT TIMES WERE NECESSARILY FALSE OR FRAUDULENT, AND AVENTIS KNEW THAT SUCH CLAIMS WERE FALSE OR FRAUDULENT.

198. Because of Aventis' illegal promotion of certain off-label uses of Taxotere, and because Aventis engaged in the Fraudulent Marketing Scheme, which included unlawful kickbacks to physicians and healthcare providers, as described more fully above, the claims for payment for Taxotere by the providers were false and fraudulent and not eligible for reimbursement pursuant to Governmental medical reimbursement regulations.

199. Because every claim submitted for reimbursement pursuant to a Governmental medical reimbursement system is paid only if the healthcare provider has certified that the services rendered are eligible for reimbursement under Federal law and in compliance with Federal laws, claims for payment submitted to and paid by a Governmental medical reimbursement system for the prescription of Taxotere as a result of Aventis' Fraudulent Marketing Scheme were necessarily false or fraudulent claims for payment during all times relevant to this Complaint and, thus, Aventis' Fraudulent Marketing Scheme utilized false statements and records to get false claims paid and caused such false claims to be submitted to the Government. But for Aventis' Fraudulent Marketing Scheme, healthcare providers would not have been unlawfully influenced to prescribe Taxotere, and had the Government known of the Fraudulent Marketing Scheme, it would not have paid for such claims.

## COUNT I

## Conspiracy To Violate The False Claims Act – 31 U.S.C. §3729(a)(3)

200. Paragraphs 1-199 are incorporated as set forth at length herein.

201. Between at least 1996 to January 2004, the Defendant Aventis, various healthcare providers, Aventis' outside consultants, and members of Aventis' sales force, knowingly combined and conspired with each other to violate the False Claims Act by acting in concert to defraud the Government by getting fraudulent claims allowed and paid relating to Taxotere in violation of 31 U.S.C. §§ 3729(a)(3).

202. The healthcare providers that submitted false claims for payment to the Government include, but are not limited to, Hospitals A-G, Group Practices A-E, and the John Doe Defendants. The false claims submitted by the herein identified healthcare providers include, but are not limited to, the demands for reimbursement for the prescription of Taxotere when it was not medically necessary and, thus, ineligible for federal reimbursement. The false statements made are more fully described above in the Fraudulent Marketing Scheme involving the unlawful promotion of Taxotere.

203. Certain documents, records and other materials that provide evidence of the Fraudulent Marketing Scheme and the false claims for payment made to the Government between 1996 and January 2004 are in the possession or control of Defendant Aventis, third-party healthcare providers, or other entities or persons over whom Plaintiff has no control or responsibility. The documents, records and other materials in the possession of Defendant Aventis include, but are not limited to, healthcare claim forms, marketing presentations, communications to sales representatives, ledgers showing payment to healthcare providers, records demonstrating marketing activity directed at healthcare providers, records of sample distribution, Aventis Managers' and Sales Specialists' annual business plans and significant activity reports, Aventis Oncology Sales Specialists' weekly reports, corporate policies and procedures generated and maintained by Aventis, logs of Aventis speaker presentations, minutes

of board meetings, records of meetings of the Oncology Department, sales statistics, spreadsheets, and training materials. The documents, records and other materials in the possession of third parties include, but are not limited to, claims made to the Government for reimbursement, medical records and patient charts, records of prescriptions, records of payments received from the Government, records evidencing meetings with members of Aventis' sales force, and communications between the third parties, Aventis and members of its sales force. The documents, records and other information that evidence the Fraudulent Marketing Scheme are available from Defendant and other third parties and will be obtained through discovery.

204. The false claims and statements made and caused to be made by Aventis and its co-conspirators in furtherance of the conspiracy are set forth in detail above.

**WHEREFORE** Plaintiff/Relator, Yoash Gohil, acting on behalf of the United States of America, demands that Defendants pay the United States of America the penalty of not less than $6,000 and not more than $11,000 per violation of the False Claims Act committed by Aventis and the John Doe Defendants; treble the damages which the United States of America has sustained because of the violations of the False Claims Act, with such violations occurring between 1996 and January 2004 and including, but not limited to, the claims for reimbursement for prescriptions of Taxotere and false statements made by the herein identified healthcare providers relating to the unlawful promotion of Taxotere; plus litigation costs and reasonable attorneys fees, and other such relief as the Court deems appropriate.

## COUNT II

**Violations Of The Federal Anti-Kickback Act**
**As Violations Of The False Claims Act – 31 U.S.C. § 3729(a)(2)**

205. Plaintiff incorporates paragraphs 1-204 as if fully set forth herein.

206. Defendant Aventis violated 42 U.S.C. §1320a-7b(b)(1) because it knowingly and willfully paid remuneration to healthcare providers in return for arranging for the furnishing and recommending of goods and services for which payment was made under a Federal healthcare program relating to Taxotere in violation of 42 U.S.C. §1320a-7b(b)(1)(A) and (B).

207. Aventis knowingly caused the submission of false and fraudulent claims and charges by healthcare providers to whom Taxotere was sold because those providers were caused to submit false claims, use false statements and records to get false and fraudulent claims paid as a direct result of Aventis' violations of the Anti-Kickback Act.

208. Providers of service participating in the Medicare program are required by Soc. Sec. Act §1815(a) to submit to the Department of Health and Human Services information regarding the cost relating to healthcare services furnished to Medicare beneficiaries. Medicare regulations also state that cost reports are required from providers on an annual basis.

209. The cost reports on the Form HCFA-2552 and the certifications contained therein were filed by certain Aventis customers who purchased goods and/or services from it. Each Form HCFA-2552 contained a certification that each cost report submitted to the Government was not infected by a kickback or other unlawful activity, and included costs and expenses for goods and/or services provided by or on behalf of Aventis for which healthcare providers received unlawful remuneration in the form of price reductions, incentives, gifts, and/or bonuses in violation of 42 U.S.C.A. 1320a-7b(b), thus causing the certifications on Form HCFA-2552 to be "false records or statements."

210. Medicare would not have reimbursed Aventis' customers if it had known that Aventis' customers submitted false and fraudulent documents in order to obtain higher Medicare reimbursement, or if it had known about Aventis' underlying violations of the Anti-Kickback Act.

211. Aventis knew that the statements submitted by its healthcare provider customers consisted of false certifications on the annual cost reports in that its customers certified their compliance with all Federal and State laws, yet acted in violation of the Anti-Kickback Act. Aventis further knew that, by providing kickbacks to healthcare providers, it was causing providers to violate their Provider Agreements.

212. The submission of thousands of claims for payment by Aventis' customers contained false certifications that they were complying with Federal healthcare laws and regulations, including the Anti-Kickback Act, when, in fact, they were not. Each failure of Aventis' customers to announce their non-compliance with the Anti-Kickback Act constituted a violation of the False Claims Act. The healthcare providers that submitted false claims for payment include, but are not limited to, Hospitals A-G, Group Practices A-E, and the John Doe Defendants.

213. The submission for approval of the Form HCFA-2552s, which falsely certified compliance with all applicable laws, and the above discussed illegal actions by Aventis, violate the explicit prohibitions of 31 U.S.C.A. 3729(a)(2) of the False Claims Act.

**WHEREFORE** Plaintiff/Relator, Yoash Gohil, acting on behalf of the United States of America, demands that Defendants pay the United States of America the penalty of not less than $6,000 and not more than $11,000 per violation of the False Claims Act committed by Aventis and the John Doe Defendants; treble the damages which the United States of America has

sustained because of the violations of the False Claims Act, with such violations occurring between 1996 and January 2004 and including, but not limited to, the claims for reimbursement for prescriptions of Taxotere and false statements made by the herein identified healthcare providers relating to the unlawful promotion of Taxotere; plus litigation costs and reasonable attorneys fees, and other such relief as the Court deems appropriate.

## COUNT III

### Violation Of 31 U.S.C.A. §3729(a)(1)

214. Paragraphs 1-213 are incorporated as set forth at length herein.

215. Between at least 1996 and January 2004, Aventis, pursuant to the Fraudulent Marketing Scheme, as described above, and by the false certification of compliance with federal regulations, knowingly submitted and/or caused to be submitted false and fraudulent claims for payment or approval to Medicare, Medicaid, Champus/Tricare, and other federal reimbursement programs relating to Taxotere in violation of 31 U.S.C.A. §3729(a)(1), as more fully described herein. The healthcare providers that submitted false claims for payment include, but are not limited to, Hospitals A-G, Group Practices A-E, and the John Doe Defendants.

216. Aventis' actions, which caused the submission of false and fraudulent claims for payment or approval to the Government, caused the Government to suffer damages and pay funds to Defendants to which they were not entitled.

**WHEREFORE** Plaintiff/Relator, Yoash Gohil, acting on behalf of the United States of America, demands that Defendants pay the United States of America the penalty of not less than $6,000 and not more than $11,000 per violation of the False Claims Act committed by Aventis and the John Doe Defendants; treble the damages which the United States of America has sustained because of the violations of the False Claims Act, with such violations occurring

between 1996 and January 2004 and including, but not limited to, the claims for reimbursement for prescriptions of Taxotere and false statements made by the herein identified healthcare providers relating to the unlawful promotion of Taxotere; plus litigation costs and reasonable attorneys fees, and other such relief as the Court deems appropriate.

## COUNT IV

## Violation Of 31 U.S.C.A. §3729(a)(2)

217. Paragraphs 1-216 are incorporated as set forth at length herein.

218. Between at least 1996 and January 2004, Aventis, by the Fraudulent Marketing Scheme, and/or by the false certification of compliance with federal regulations, knowingly caused to be made and used false records and statements, and caused to be submitted false records and statements, to get false and fraudulent claims paid and approved by the Government relating to Taxotere in violation of 31 U.S.C.A. §3729(a)(2), as more fully described herein.

219. Aventis' actions, which caused the submission of false records and statements to the Government, caused the Government to suffer damages and pay funds to Defendants to which they were not entitled.

**WHEREFORE** Plaintiff/Relator, Yoash Gohil, acting on behalf of the United States of America, demands that Defendants pay the United States of America the penalty of not less than $6,000 and not more than $11,000 per violation of the False Claims Act committed by Aventis and the John Doe Defendants; treble the damages which the United States of America has sustained because of the violations of the False Claims Act, with such violations occurring between 1996 and January 2004 and including, but not limited to, the claims for reimbursement for prescriptions of Taxotere and false statements made by the herein identified healthcare

providers relating to the unlawful promotion of Taxotere; plus litigation costs and reasonable attorneys fees, and other such relief as the Court deems appropriate.

**JURY TRIAL DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury on all issues.

Date: May 13, 2015

STEPHEN M. ORLOFSKY - 31633
NICHOLAS C. HARBIST - 35210
BLANK ROME LLP
One Logan Square
Philadelphia, PA 19103
(215) 569-5366

CARL D. POPLAR
CARL D. POPLAR, P.A.
1010 Kings Highway South, Building 2
Building Two
Cherry Hill, NJ 08034
(856) 216-9979
*Admiteed Pro Hac Vice*

*Attorneys for Plaintiff/Relator,*
*Yoash Gohil*

BLANK ROME LLP
A Pennsylvania LLP
STEPHEN M. ORLOFSKY (Pa. ID 31633)
NICHOLAS C. HARBIST (Pa. ID 35210)
One Logan Square
130 North 18th Street
Philadelphia, PA 19103-6998
(215) 569-5500

CARL D. POPLAR, P.A.
CARL D. POPLAR (*Pro Hac Vice*)
1010 Kings Highway South, Building 2
Cherry Hill, NJ 08034
(856) 216-9979

*Attorneys for Plaintiff/Relator, Yoash Gohil*

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

| | |
|---|---|
| UNITED STATES OF AMERICA ex. rel. YOASH GOHIL,<br><br>Plaintiff/Relator,<br><br>vs.<br><br>SANOFI-AVENTIS U.S. INC.; AVENTIS, INC., AVENTIS PHARMACEUTICALS, INC., and JOHN DOES #1-50, FICTITIOUS NAMES,<br><br>Defendants. | No. 02-cv-2964 |

**CERTIFICATE OF SERVICE**

I hereby certify that on this 13th day of May, 2015, I caused Plaintiff/Relator Yoash Gohil's Third Amended Complaint to be filed with the Court. In addition, I caused true and correct copies of the foregoing to be served on the following persons:

**BY HAND**

Richard L. Scheff, Esq.
Montgomery McCracken Walker & Rhoads, LLP
123 South Broad Street
Philadelphia, PA 19109

Susan Bricklin, Esq.
Assistant United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106

**BY OVERNIGHT MAIL**

Robert J. McCully, Esq.
Shook Hardy & Bacon, LLP
2555 Grand Boulevard
Kansas City, MO 64105

STEPHEN M. ORLOFSKY