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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF IOWA, THE STATE OF LOUISIANA, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, THE STATE OF WASHINGTON, AND THE DISTRICT OF COLUMBIA, *EX REL.* JESSICA PENELOW and CHRISTINE BRANCACCIO, Plaintiffs, vs. JANSSEN PRODUCTS, LP, Defendant.	CASE NO. 12-cv-07758-MAS-LHG **JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 *ET SEQ.* AND PENDENT STATE FALSE CLAIMS ACTS

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COMPLAINT

The *qui tam* Relators, Jessica Penelow ("Relator Penelow") and Christine Brancaccio ("Relator Brancaccio") (collectively, "Relators"), on behalf of the United States of America, The State of California, The State of Colorado, The State of Connecticut, The State of Delaware, The State of Florida, The State of Georgia, The State of Hawaii, The State of Illinois, The State of Indiana, The State of Iowa, The State of Louisiana, The Commonwealth of Massachusetts, The State of Michigan, The State of Minnesota, The State of Montana, The State of Nevada, The State of New Jersey, The State of New Mexico, The State of New York, The State of North Carolina, The State of Oklahoma, The State of Rhode Island, The State of Tennessee, The State of Texas, The Commonwealth of Virginia, The State of Washington and The District of Columbia (hereinafter referred to as the "Relator States" and collectively with the United States as the "Government Plaintiffs"), bring this action against Janssen Products, LP ("Defendant" or "Janssen") for violations of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.* and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, as well as for violations of the following state false claims acts: The California False Claims Act, § 12650, *et seq.*; The Colorado Medicaid False Claims Act, § 25.5-4-304, *et seq.*; The Connecticut False Claims Act, § 17b-301a, *et seq.*; The Delaware False Claims and Reporting Act, § 1201, *et seq.*; The Florida False Claims Act, § 68.081, *et seq.*; The Georgia State False Medicaid Claims Act, § 49-4-168, *et seq.*; The Hawaii False Claims Act, § 661-21, *et seq.*; The Illinois False Claims Act, § 175/1, *et seq.*; The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-1, *et seq.*; The Iowa False Claims Act, §685.1, *et seq.*; The Louisiana False Claims Act, § 46:437.1, *et seq.*; The Massachusetts False Claims Act, Ch. 12 § 5A, *et seq.*; The Michigan Medicaid False Claim Act, § 400.601, *et seq.*; The Minnesota False Claims Act, § 15C.01, *et seq.*; The Montana False Claims Act, § 17-8-401, *et seq.*; The Nevada Submission of False Claims to State or Local Government Act, § 357.010, *et*

seq.; The New Jersey False Claims Act, § 2A:32C-1, *et seq.*; The New Mexico Medicaid False Claims Act, § 27-14-1, *et seq.*; The New York False Claims Act, § 187, *et seq.*; The North Carolina Medical Assistance Provider False Claims Act, § 108A-70.10, *et seq.*; Oklahoma Medicaid Program Integrity Act §1005(A)(6); The Rhode Island False Claims Act, § 9-1.1-1, *et seq.*; The Tennessee Medicaid False Claims Act, § 71-5-181, *et seq.*; The Texas Medicaid Fraud Prevention Act, § 36.001, *et seq.*; The Virginia Fraud Against Taxpayers Act, § 8.01-216.1, *et seq.*; The Washington Health Care False Claim Act, § 48.80.010, *et seq.*; The District of Columbia False Claims Act, § 2-381.01, e*t seq* (hereinafter referred to as the "State False Claims Acts"), to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts.

The relevant state and federal programs that paid for prescriptions of Prezista and Intelence based on Janssen's fraudulent course of conduct are referred to herein as the Government Health Care Programs.

SUMMARY OF THE ACTION

1. This case involves the illegal, off-label marketing of two Janssen drugs, Prezista (darunavir) and Intelence (etravirine), both antiretroviral ("ARV") drugs used to treat patients infected with HIV ("human immunodeficiency virus")/AIDS ("acquired immune deficiency syndrome"). Janssen and its parent company, Johnson & Johnson ("J & J"), are companies with a long history of prior misconduct involving off-label promotion of its drugs, including the blockbuster anti-psychotic drug, Risperdal, the epilepsy drug, Topamax, and the heart failure drug, Natrecor. Despite this history, Defendant continues to market and sell the ARV drugs Prezista and Intelence with misleading, off-label marketing and kickbacks, thereby knowingly causing physicians to prescribe the drugs, and the Government Plaintiffs to reimburse for these very

expensive drugs, in violation of the Federal and State False Claims Acts and the federal Anti-Kickback Statute.

2. As set forth herein, in selling and promoting Prezista, Janssen, through its sales representatives and managers, routinely delivered false and misleading messages to physicians by: 1) promoting Prezista as "lipid-neutral" contrary to its FDA-approved label which indicates that a side effect of the drug is an increase in cholesterol and triglycerides; and 2) misstating Prezista's superiority, efficacy and potency based on the uniqueness of its "binding affinity."

3. With respect to promoting Prezista as "lipid-neutral," Janssen falsely and misleadingly claimed that the drug would *not* affect or increase a patient's cholesterol or triglyceride levels, which is directly contradicted by the FDA-approved label for Prezista. Prezista's label shows that the drug has a significant negative effect on lipids, including cholesterol and triglycerides. The label specifically lists as serious adverse drug reactions the following: high cholesterol (hypercholesterolemia), high triglycerides (hypertriglyceridemia) and an increase in LDL ("bad" cholesterol).

4. This misleading promotion, which began in 2006 and continued through 2014, is significant because heart disease caused by high cholesterol and triglycerides is a real safety threat and concern for HIV/AIDS patients. Heart disease is one of the leading causes of death for HIV/AIDS patients. Janssen's promotion of Prezista as "lipid-neutral" falsely minimizes this threat. Further, the two scientific studies on which Janssen relies to support its "lipid-neutral" promotion – the DART study and METABOLIK study – are not part of the FDA-approved label and are of questionable scientific value.

5. In addition to misleadingly promoting Prezista as lipid-neutral, beginning in and around February 2007 and continuing through the present, Defendant's sales representatives and

managers have made unsupported claims regarding Prezista's superiority, efficacy and potency based on its purported superior "binding affinity." "Binding affinity" refers to the way in which Prezista works in a patient's body. Prezista belongs to the Protease Inhibitor ("PI") class of drugs. All PI drugs work the same way by binding to the active site of the HIV protease (an enzyme critical for viral replication) and inhibiting it from replicating.

6. Defendant misleadingly claimed that compared with other PI drugs, Prezista is a stronger, more potent and efficacious drug with superior binding affinity which would prevent the HIV virus from mutating, and thus prevent drug resistance. However, Janssen's claims of superior binding affinity are misleading because they are based on a clinical study which is not included in the drug's FDA-approved labeling and is of limited scientific value because it was done by Tibotec, (now known as Janssen), whose scientists conducted the study. Tibotec funded the study and the study was performed in a lab, and not on HIV-infected patients.

7. This misleading promotion was widely utilized despite the fact that in around 2007-2008, Janssen had been instructed by the FDA to *remove* information regarding superior binding affinity from early Prezista promotional materials because the claim was not adequately supported.

8. Further, as recently as September 2015 at a national sales meeting in Philadelphia (called a Plan of Action or POA meeting), Janssen continued to train its sales representatives on how to proactively promote Prezista based on its binding affinity.

9. With regard to Intelence, beginning in 2008 and continuing through September 2014, Defendant engaged in the off-label promotion of Intelence in two ways: 1) as safe and effective for once-daily dosing; and 2) as safe and effective for "treatment-naïve" patients (patients who had never taken any ARV medications). These two promotions were directly contradicted by Intelence's FDA-approved label stating that the drug *must be taken twice a day* and is indicated

for treatment of HIV-1 infection in *treatment-experienced patients* (those who had previously taken ARV medications). These off-label promotions are false and misleading because they promote the drug for a dosing regimen (*e.g.,* once-daily) and patient population (*e.g.,* treatment-experienced) not specified on the label nor approved by the FDA as safe and effective for treatment of patients.

10. With regard to promoting Intelence for once-daily dosing contrary to the label specifying twice-daily dosing, Defendant engaged in this promotion in order to increase sales and compete with other more convenient ARV drugs which only needed to be taken once a day. Once-daily dosing is easier for patients to follow and more appealing, but if a patient does not carefully follow the FDA-indicated dosing drug regimen, their HIV viral load can increase, potentially weakening the drug's ability to fight the disease. Defendant's sales representatives and managers made false and misleading statements to physicians and relied on small, not scientifically valid studies in promoting once-daily Intelence as safe and effective.

11. Additionally, Defendant fraudulently promoted Intelence as safe and effective for "treatment-naive patients" – HIV-positive patients who had not previously been treated with ARV medication – when in fact the drug is only indicated for treatment-experienced patients. By marketing Intelence for treatment of an additional class of treatment-naïve patients and not limiting its promotions to only treatment-experienced patients, Defendant sought to increase sales of its drug. Defendant's sales representatives and managers made false and misleading statements and relied on a small, insignificant study to support the safety and efficacy of prescribing Intelence for treatment-naïve patients.

12. Prescribing Intelence to treatment-naive patients harmed these patients and decreased the chance that they could successfully treat HIV over the course of their lives.

Guidelines recommended by the Department of Health and Human Services and the International AIDS Society set forth recommendations concerning the sequencing of cocktails – i.e. the order of drug cocktails that should be administered to patients. This sequencing is designed to maximize treatment options for patients with HIV if their virus becomes resistant to the drugs that they are taking. Following the recommended sequencing of drugs enables physicians to save drugs that are more potent against resistant strains of HIV that emerge as a patient progresses through disease. Prematurely using Intelence could cause patients to run out of drug options as their disease progresses. Without a good drug treatment option, the patient's virus will continue to replicate and potentially lead to the death of the patient.

13. Janssen delivered these misleading messages regarding Prezista and Intelence during sales calls, dinner programs and speaker programs nationwide. Furthermore, as alleged herein, Janssen's payments to speakers at the dinner programs and speaker programs amounted to kickbacks in violation of the Anti-Kickback Statute. These speakers were paid an increasing honorarium based upon the level of prescriptions they wrote and their market share of the drugs. Janssen calculated market share as the percentage of Janssen drugs that a doctor prescribes in a class compared to non-Janssen drugs in that class (Prezista belongs to the PI class of drugs and Intelence belongs to the "NNRTI" class, non-nucleoside reverse-transcriptase inhibitors). Prescribing speakers with a high market share would be paid $2,500 per program (as opposed to $2,000) and a speaker with a low market share would ultimately be dismissed from the speaker bureau.

14. The amount of these kickbacks was material to doctors. For example, Dr. Donald Kaminsky, a physician who practices in Manhattan, stated to Relator Penelow that he wouldn't be able to pay for his mortgage without the honorarium he receives for his talks from Janssen.

Moreover, Dr. Kaminsky told Relator Penelow that he was willing to say whatever Janssen and Nancy Bartnett (a Janssen Key Account Manager) told him to say, even if such messages were off-label.

15. By selling and promoting Prezista and Intelence off-label, Defendant knowingly and misleadingly influenced physicians' medical judgments in deciding which drugs to prescribe. In treating HIV/AIDS patients, physicians typically prescribe a combination or "cocktail" of ARV drugs. Different factors such as the drug's effect on a patient's lipids or the dosing regimen required (twice-a-day vs. once-a-day) are important considerations. Defendant knowingly misled doctors to increase profits at the expense of the Government Plaintiffs by engaging in fraudulent and off-label marketing.

16. At all relevant times, Defendant was fully aware that the Government Plaintiffs reimbursed a substantial portion of Prezista and Intelence prescriptions. A significant percentage of HIV/AIDS patients are enrolled in Medicare/Medicaid. In sum, through the illegal conduct detailed herein, Defendant caused untold numbers of claims tainted by the off-label marketing, misbranding, and kickback schemes to be submitted to the Government Plaintiffs for reimbursement.

THE PARTIES

17. Defendant Janssen Products, LP ("Janssen") is a subsidiary of Johnson & Johnson and incorporated in New Jersey with its principal place of business in Titusville, NJ. At all relevant times herein, Janssen marketed and sold Prezista and Intelence through an illegal, off-label marketing campaign, which included kickbacks to doctors, in this District and nationwide.

18. The United States is a plaintiff to this action. The United States brings this action on behalf of the Department of Health and Human Services ("DHHS") and the Centers for

Medicare and Medicaid Services ("CMS") which administer the Medicare and Medicaid Programs.

19. The State of California ("California") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in California and were covered Medicaid benefits under California's Medi-Cal Program.

20. The State of Colorado ("Colorado") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Colorado and were covered Medicaid benefits under Colorado's Medicaid Program.

21. The State of Connecticut ("Connecticut") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Connecticut and were covered Medicaid benefits under Connecticut's Medicaid Program.

22. The State of Delaware ("Delaware") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Delaware and were covered Medicaid benefits under Delaware's Medicaid Program.

23. The State of Florida ("Florida") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Florida and were covered Medicaid benefits under Florida's Medicaid Program.

24. The State of Georgia ("Georgia") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Georgia and were covered Medicaid benefits under Georgia's Medicaid Program.

25. The State of Hawaii ("Hawaii") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Hawaii and were covered Medicaid benefits under Hawaii's Medicaid Program.

26. The State of Illinois ("Illinois") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Illinois and were covered Medicaid benefits under Illinois' Medicaid Program.

27. The State of Indiana ("Indiana") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Indiana and were covered Medicaid benefits under Indiana's Medicaid Program.

28. The State of Iowa ("Iowa") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Iowa and were covered Medicaid benefits under Iowa's Medicaid Program.

29. The State of Louisiana ("Louisiana") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Louisiana and were covered Medicaid benefits under Louisiana's Medicaid Program.

30. The Commonwealth of Massachusetts ("Massachusetts") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Massachusetts and were covered Medicaid benefits under Massachusetts' Medicaid Program.

31. The State of Michigan ("Michigan") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Michigan and were covered Medicaid benefits under Michigan's Medicaid Program.

32. The State of Minnesota ("Minnesota") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Minnesota and were covered Medicaid benefits under Minnesota's Medicaid Program.

33. The State of Montana ("Montana") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Montana and were covered Medicaid benefits under Montana's Medicaid Program.

34. The State of Nevada ("Nevada") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Nevada and were covered Medicaid benefits under Nevada's Medicaid Program.

35. The State of New Jersey ("New Jersey") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in New Jersey and were covered Medicaid benefits under New Jersey's Medicaid Program.

36. The State of New Mexico ("New Mexico") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in New Mexico and were covered Medicaid benefits under New Mexico's Medicaid Program.

37. The State of New York ("New York") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in New York and were covered Medicaid benefits under New York's Medicaid Program.

38. The State of North Carolina ("North Carolina") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to

Medicaid recipients in North Carolina and were covered Medicaid benefits under North Carolina's Medicaid Program.

39. The State of Oklahoma ("Oklahoma") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Oklahoma and were covered Medicaid benefits under Oklahoma's Medicaid Program.

40. The State of Rhode Island ("Rhode Island") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Rhode Island and were covered Medicaid benefits under Rhode Island's Medicaid Program.

41. The State of Tennessee ("Tennessee") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Tennessee and were covered Medicaid benefits under Tennessee's Medicaid Program.

42. The State of Texas ("Texas") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Texas and were covered Medicaid benefits under Texas' Medicaid Program.

43. The Commonwealth of Virginia ("Virginia") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Virginia and were covered Medicaid benefit under Virginia's Medicaid Program.

44. The State of Washington ("Washington") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Washington and were covered Medicaid benefits under Washington's Medicaid Program.

45. The District of Columbia ("DC") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in DC and were covered Medicaid benefits under DC's Medicaid Program.

46. Relator, Jessica Penelow, is a citizen of the United States and resides at 30 Heron Road, Livingston, New Jersey 07039. Relator has standing to bring this action pursuant to 31 U.S.C. § 3730(b)(1) and the relevant provisions of the State False Claims Acts. Relator brings this action on behalf of the United States for violations of the Federal False Claims Act and on behalf of each Relator State named herein for violations of its respective State False Claims Act.

47. Relator Penelow graduated from Florida Atlantic University in 1998 with a B.S. in health care administration and management and from St. Joseph's College in 2012, with an MS in Health Care Management and in 2013, with an MBA. Relator started as a Senior Virology Sales Consultant at Tibotec Therapeutics ("Tibotec") in 2006 and held that position until June 2013. Tibotec was a subsidiary of Johnson & Johnson and changed its name to Janssen in 2011. While at Tibotec, she marketed four HIV drugs, Edurant, Complera, Prezista and Intelence, to doctors on the Lower East Side of Manhattan. Through her employment at Janssen and her interactions with both doctors and Defendant's sales representatives and managers that solicited the doctors, Relator has uncovered the False Claims Act violations against Janssen detailed herein.

48. Relator, Christine Brancaccio, is a citizen of the United States and resides at 14 White Hall Court, Holbrook, New York 11741. Relator has standing to bring this action pursuant to 31 U.S.C. § 3730(b)(1) and the relevant provisions of the State False Claims Acts. Relator brings this action on behalf of the United States for violations of the Federal False Claims Act and on behalf of each Relator State named herein for violations of its respective State False Claims Act.

49. Relator Brancaccio graduated from Dowling College in 1984 with a B.B.A. in Business Administration. Relator started as a Senior Virology Sales Representative with Ortho Biotec in 2003, which was a subsidiary of J & J, where she sold the HIV drug Procrit. Since 2006, she has worked for Janssen as a Senior Virology Sales Representative responsible for marketing Prezista, Intelence, Edurant, Complera, and Prezcobix to providers on Long Island and Queens. Through her continued employment at Janssen and her interactions with both doctors and the Defendant's sales representatives and managers that solicited them, Relator has uncovered the False Claims Act violations against Janssen detailed herein.

50. Although Relators currently possess some documentary evidence of this off-label marketing scheme, many documents detailing Janssen's illegal conduct previously on Relators' work laptop computers were destroyed by Janssen in November 2010 when Janssen IT personnel demanded that Relators give them their computers and later returned the computers scrubbed of all data.

JURISDICTION AND VENUE

51. Jurisdiction is founded upon the Federal False Claims Act (the "Act" or the "False Claims Act"), 31 U.S.C. § 3729 *et seq.*, specifically 31 U.S.C. § 3732(a) and (b), and also 28 U.S.C. §§ 1331, 1345, and is not barred by § 3730(e). The information upon which these allegations are based was voluntarily provided by Relators to the Federal Government prior to filing the Complaint pursuant to 31 U.S.C. §§ 3730(e)(4)(B) and 3730(b)(2).

52. Venue in the District of New Jersey is appropriate under 31 U.S.C. § 3732(a) and sufficient contacts exist for jurisdiction in that Defendant conducts business and sells its pharmaceuticals, including Intelence and Prezista, in the District of New Jersey. Such drugs, as Defendant knows, (1) have been and continue to be supplied to Government Health Care Program

recipients, including Medicare and Medicaid recipients and (2) have been and continue to be the subject of claims for reimbursement by drug providers to Government Health Care Programs.

53. A copy of the initial and Amended Complaints and written disclosures of substantially all material evidence and information in both Relators' possession were served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure, prior to the filing of the initial and Amended Complaints *in camera* and under seal by delivering a copy of the initial and Amended Complaints, material evidence and information to the United States Attorney General, the United States Attorney for the District of New Jersey and by sending a copy of the Complaint, material evidence and information by certified mail to the Attorneys General for California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia; and to the Chief Financial Officer of the Florida Department of Financial Services.

BACKGROUND

I. THE APPLICABLE LAW

A. The Prohibition Against Misbranding and Marketing Drugs for Off-Label Uses

1. FDA Laws and Regulations

54. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed or sold in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §§ 355(a) & (d).

55. In order for FDA approval of a new drug, the drug manufacturer must present substantial evidence of efficacy through adequate and well-controlled studies. 21 C.F.R. § 314.50(d). FDA regulations specify the characteristics of what constitutes an adequate and well-controlled study. Noting that these characteristics "have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation[,]" the regulations detail the following requirements, *inter alia*: a clear statement of the objective of the investigation and a summary of the methods of analysis actually used; a study design "that permits a valid comparison with a control" group; and adequate measures to minimize bias on the part of the subjects, observers and analysts of the data. *Id.* § 314.126(a), (b).

56. The FDA does not approve a drug for treatment of a disease in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested. The specific approved uses are called the "indications" for which the drug may be prescribed. For each approved indication, the FDA will specify particular dosages and dosage frequency determined to be safe and effective. In approving a drug for a given indication, the FDA also approves the language of the product's label (the package insert or prescribing information).

57. The FDCA defines labeling very broadly, to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m) (2006).

58. Promotional materials that do not qualify as labeling are regulated as advertising by the FDA. Although neither advertisement nor advertising is defined in the FDCA, section 352(n) and the implementing regulations demonstrate the broad nature and scope of information regulated as "advertising." Advertisements subject to section 352(n) include those "in published

journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems." Thus, in combination with its authority over promotional labeling, the FDA's regulatory oversight of prescription drug marketing extends to practically every type of material and media.

59. Use of an approved drug for any purpose other than those indications specifically approved by the FDA is referred to as an "off-label" use. Off-label uses include treating a condition not indicated on the label, treating the indicated condition at a different dosage or dosage frequency from the label's recommended dose, or treating a different patient population than those approved by the FDA.

60. Once a drug is approved as safe and effective for one indication, the FDA does not prohibit doctors from prescribing the drug for off-label uses. This is consistent with the FDA's mission to regulate drugs without interfering with the practice of medicine and doctors' discretion in treating their patients.

61. Although physicians may prescribe drugs for non-FDA-approved uses, the law prohibits drug manufacturers from selling a drug that is "misbranded." 21 U.S.C. § 331.

62. A drug is considered "misbranded" if its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a). A manufacturer illegally "misbrands" a drug if the drug's labeling, *inter alia*, describes intended uses for the drug that have not been approved by the FDA, or if there are unsubstantiated claims of efficacy or safety.

63. Further, an advertisement for a drug (as defined above) is "false, lacking in fair balance, or otherwise misleading… if it:"

> (i) Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients than has been

> demonstrated by substantial evidence or substantial clinical experience;
>
> * * *
>
> (ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience;
>
> * * *
>
> (iv) Presents 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;
>
> * * *
>
> (x) Uses literature, quotations, or references that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim;

21 C.F.R. § 202.1.

64. In sum, the FDCA prohibits drug companies from promoting approved drugs for unapproved uses or from making misleading claims as to the drug's safety or effectiveness. *See* 21 U.S.C. §§ 331, 352, 355(d). This regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body: the FDA.

65. The Pharmaceutical Research and Manufacturers of America ("PhRMA"), the industry association of drug companies, has guidelines governing drug marketing, namely the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"). In the section titled "Basis of Interactions:" the Code states that "[p]romotional materials provided to Healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and

benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications." PhRMA Code, Section 1.

2. FDA Guidance on Good Reprint Practices

66. As alleged below, Defendant relied on several unsubstantiated scientific studies in promoting Intelence and Prezista for each of the off-label marketing schemes described herein. In doing so, in addition to unlawful off-label promotion and misbranding, Defendant violated the tenants of the FDA's "Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices," ("Reprint Guidance").

67. The Reprint Guidance reflects the FDA's "current views on the dissemination of medical journal articles and medical or scientific reference publication on unapproved uses of approved drugs." *Available at* http://www.fda.gov/oc/op/goodreprint.html (Jan. 2009). The Guidance applies if a manufacturer is distributing scientific and medical information concerning safety and effectiveness of a non-FDA-approved use for a drug.

68. Among other criteria, the Guidance states that the information contained in the scientific or medical journal article "should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts." Further, the type of scientific or medical journal article distributed should be "peer-reviewed" and not "in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article."

69. In addition, there are several requirements regarding the manner in which to disseminate the scientific and medical information. The scientific or medical journal article should be accompanied by the approved labeling for the drug, and should be distributed separately from

promotional material. If it is being distributed by a sales representative, it "should not be the subject of discussion between the sales representative and the physician during the sales visit."

70. These same guidelines were reaffirmed in the February 2014 updated draft version of "Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices," *available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf*.

B. The Prohibition Against Kickbacks

1. The Anti-Kickback Statute

71. As alleged below, Janssen's payments to high-prescribing physicians to speak at dinner and speaker programs amounted to kickbacks in violation of the "Anti-Kickback" Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(2)(B) and relevant state Anti-Kickback Statutes. The AKS prohibits the payment of any remuneration to any person in order to induce that person to "purchase, lease, order, arrange for or recommend purchasing, leasing or ordering any good, facility, service or item" for which reimbursement may be made under a Federal health program. Anyone found guilty of offering or paying kickbacks in violation of the Anti-Kickback Statute shall be guilty of a felony.

72. Specific intent is not required to establish a violation of the AKS. That is, "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." 42 U.S.C. § 1320(a)-7b(h)).

73. A "Federal health care program" is defined at 42 U.S.C. § 1320a-7b(f) as any plan or program providing health benefits funded, whether directly or indirectly, by the United States Government. The Anti-Kickback Statute applies to claims for reimbursement of Prezista and Intelence prescriptions submitted to the Government Health Care Programs, including Medicare

and Medicaid. Any violation of the AKS in connection with a claim for payment from a Government Health Care Program is a false claim. 42 U.S.C. § 1320(a)-7(b)(g).

2. Relevant Guidance

74. The OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (the OIG Guidance), also provides direction as to what constitutes a violation of AKS. The OIG Guidance states that "[a]ny time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals."

75. The government determines whether the arrangement between a pharmaceutical manufacturer and a physician violates the AKS "in light of the totality of all facts and circumstances, bearing in mind the following facts, among others:"

- Nature of the relationship between the parties. What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer?
- Manner in which the remuneration is determined. Does the remuneration take into account, directly or indirectly, the volume or value of business generated (e.g., is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer's product)?
- Value of the remuneration. Is the remuneration more than trivial in value?
- Potential federal program impact of the remuneration. Does the remuneration have the potential to affect costs to any of the federal health care programs or their beneficiaries or to lead to overutilization or inappropriate utilization?
- Potential conflicts of interest. . . . If the remuneration relates to the dissemination of information, **is the information complete, accurate, and not misleading**?

68 Fed. Reg. at 23737 (emphasis added).

76. In light of those factors, payments and other inducements given to physicians described herein constitute unlawful kickbacks.

3. The PhRMA Code

77. Janssen's parent company, J & J, is a member of PhRMA and a signatory to the PhRMA Code, PhRMA's guidelines governing drug marketing.

78. As alleged below, Janssen delivered misleading and off-label messages to health care professionals at, *inter alia*, dinner and speaker programs nationwide. The PhRMA Code, revised July 2008, includes the following applicable section prohibiting this conduct (emphasis added):

- Section 7 – "Speaker Programs and Speaker Training Meetings": When a pharmaceutical company hires a healthcare professional to help educate other healthcare professionals about the company's products, the company is responsible and accountable for the content of the speech. Speakers should "clearly identify the company that is sponsoring the presentation… and that the speaker is presenting information that is consistent with FDA guidelines." "Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communication skills. **Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment."**

II. THE RELEVANT GOVERNMENT HEALTH CARE PROGRAMS

79. The Government Health Care Programs referenced herein include Medicaid and Medicare, discussed more fully in Sections A and B below, and encompass any health care plan or program that provides health benefits, whether funded directly, in whole or in part, by the United States or the Relator States such as, for example, ADAP (AIDS Drug Assistance Program), the Ryan White CARE Act and HDAP (HIV Drug Assistance Program in Massachusetts).

A. The Medicaid Program

80. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Enacted in 1965, the Medicaid Program functions

as a jointly-funded cooperative undertaking between the Federal and State Governments. Each State administers its own Medicaid program, but the State's programs are governed by Federal statutes, regulations and guidelines.

81. Many individuals with HIV/AIDS become indigent as a result of not being able to work due to illness. There are more than 230,000 AIDS patients on Medicaid, as of March 2013. *See* The Henry J. Kaiser Family Foundation, *Medicaid and HIV/AIDS*, Mar. 2013. Medicaid is the "single largest source of coverage for people with HIV in the U.S." *Id*.

82. The federal portion of States' Medicaid payments, the Federal Medical Assistance Percentage, is based on a State's per capita income compared to the national average. The federal portion consisted of a minimum of 50% up to a maximum of roughly 80%. However, for 2014 through 2016, "the federal government will finance 100% of the costs for individuals newly eligible for Medicaid" under the Affordable Care Act. *See* The Henry J. Kaiser Family Foundation, *Medicaid and HIV/AIDS*, Mar. 2013. Previously, for 2012, for example, the federal portion of Medicaid spending on HIV/AIDS was estimated to be $5.3 billion and the total state spending to be $4.3 billion. *Id.*

83. The States (and the District of Columbia) are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for Federal funds for Medicaid expenditures. 42 U.S.C. § 1396a(a)(30)(A).

84. Benefits for drugs are optional, but all States, including those named herein, have opted to provide Medicaid drug reimbursement coverage.

85. Medicaid drug reimbursement coverage is limited to "covered outpatient drugs" which are drugs used for "a medically accepted indication." A "medically accepted indication" means any use or indication which is approved by the FDA or which is supported by one or more

citations in certain drug compendia. *See* 42 U.S.C. § 1396r-8(k)(6) and (g)(1)(B)(i). The relevant drug compendia are: American Hospital Formulary Service (AHFS) Drug Information, United States Pharmacopeia-Drug Information (USP DI) (or its successor publications) and the DRUGDEX Information System. *See* 42 U.S.C. § 1396r-8(g)(1)(B)(i). At all relevant times, the cost of providing Intelence and Prezista for off-label uses to Medicaid recipients was not covered by Medicaid because the off-label uses were neither approved by the FDA nor supported by one or more citations included in any of the specified drug compendia.

86. Further, Medicaid (as well as Medicare and other Government Health Care Programs) only reimburses for "reasonable and necessary" medical services, including drugs. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1). That is, Medicaid and other Government Health Care Programs only cover medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." *Id.* At all relevant times, prescriptions for Intelence and Prezista for off-label uses and/or as a result of Defendant's false and misleading promotions were ineligible for Medicaid reimbursement as they were not "reasonable and necessary" for the treatment of patients.

B. The Medicare Program

87. The Medicare Program is the federally financed health insurance system for persons who are aged 65 and over, for those who are disabled and for those suffering from end-stage renal disease. On January 1, 2006, the Medicare Part D prescription drug benefit went into effect. Medicare Part D subsidizes the cost of prescription drugs for Medicare beneficiaries. *See* Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*.

88. The Medicare Part D prescription drug benefit is offered by private prescription drug plans ("PDPs") and Medicare Advantage prescription drug plans ("MA-PDs"). Medicare

beneficiaries have a choice among many different plans in each state. Medicare reimburses the private plans for its coverage of Medicare beneficiaries.

89. Medicare Part D covers the cost of FDA-approved prescription drugs used for "a medically accepted indication." *See* 42 U.S.C. §§ 1395w-102(e)(1), 1395w-151(a)(2). Just as in the Medicaid Program, for Medicare reimbursement, a "medically accepted indication" means any use or indication which is approved by the FDA or which is supported by one or more citations in certain drug compendia: AHFS Drug Information, USP DI (or its successor publications) and the DRUGDEX Information System. *See* 42 U.S.C. § 1396r-8(k)(6) and (g)(1)(B)(i). In sum, Part D drug coverage excludes drugs not approved by the FDA, and those not for use for a medically accepted indication. At all relevant times herein, the costs of providing Prezista and Intelence were not covered Medicare drugs where they were misbranded and/or prescribed off-label.

90. Further, Medicare (as well as Medicaid and other Government Health Care Programs) only reimburses for "reasonable and necessary" medical services, including drugs. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1). That is, Medicare and other Government Health Care Programs only cover medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." *Id.* At all relevant times, prescriptions for Intelence and Prezista for off-label uses and/or as a result of Defendant's false and misleading promotions were ineligible for Medicare reimbursement as they were not "reasonable and necessary" for the treatment of patients.

91. Many AIDS patients who are under 65 nonetheless qualify for Medicare coverage because they are disabled. In addition, many low-income and disabled AIDS patients are dual eligibles – those who qualify for both Medicare and Medicaid. In the case of dual eligibles, Medicare is the primary source of drug coverage.

92. Medicare spending for care of HIV/AIDS beneficiaries in fiscal year 2012 amounted to $5.8 billion. *See* The Henry J. Kaiser Family Foundation, *Medicaid and HIV/AIDS*, Mar. 2013, Figure 2.

III. BACKGROUND REGARDING HIV/AIDS & TREATMENT

93. As explained by the National Institutes of Health, AIDS was first reported in the United States in 1981 and has since become a major worldwide epidemic. AIDS is caused by HIV. By killing or damaging the cells of the immune system, HIV progressively destroys the body's immune system and ability to fight infections and cancer. The most obvious effect of HIV infection is a decline in the number of CD4 cells found in the blood, an integral part of the immune system's key infection fighters. The virus slowly disables or destroys these cells. The term AIDS applies to the most advanced stages of HIV infection.

94. There are currently six different classes of ARV drugs that stop the HIV replication process at different stages of development: entry inhibitors, fusion inhibitors, nucleoside/nucleotide reverse transcriptase inhibitors ("NRTIs"), non-nucleoside reverse-transcriptase inhibitors ("NNRTIs"), integrase inhibitors ("II") and protease inhibitors ("PIs"). Prezista belongs to the PI class of drugs and Intelence is an NNRTI.

95. Guidelines for AIDS treatment are published by the Department of Health and Human Services (the "DHHS Guidelines"). At all relevant times herein, the DHHS Guidelines have recommended that patients take a combination of three or more medications in a regimen called Highly Active Antiretroviral Therapy (HAART). For people taking HIV antiretroviral drugs for the first time, a combination regimen generally consists of two NRTIs and one active drug from one of the following classes: NNRTI, PI (generally boosted with ritonavir), II, or entry inhibitor.

96. HAART recommends taking three drugs at once because clinical studies show that HIV becomes resistant when only one drug is used. When a three drug cocktail is prescribed, if the HIV mutates to become resistant to one drug, the other two drugs may prevent that mutant HIV strain from replicating: this makes it more difficult for a resistant HIV strain to become dominant in the body. Furthermore, the chances are relatively low that HIV will develop three mutations that create resistance to three drugs and still maintain the ability to reproduce. By attacking HIV in different ways, the viral load is reduced and the chance of HIV developing resistance is decreased. Therefore, it is critical that patients take a cocktail of three drugs that are effective in slowing HIV replication in the body.

97. Adherence to a treatment regimen is very important. AIDS treatment regimens can be complicated in that they involve taking many pills at different times of the day with or without food. Correctly following a regimen can be difficult for many people, especially those who are sick or suffering side effects. Nonetheless, adherence is important because it impacts how well the drug works (if you miss a dose, HIV has an opportunity to replicate) and helps prevent drug resistance (if you miss a dose, you may develop strains of HIV that are resistant to ARV drugs). "Adherence to antiretroviral therapy (ART) has been correlated strongly with HIV viral suppression, reduced rates of resistance, an increase in survival, and improved quality of life." *Limitations to Treatment Safety and Efficacy: Adherence to Antiretroviral Therapy*, http://www.aidsinfo.nih.gov/Guidelines/HTML/1/adult-and-adolescent-treatment-guidelines/30/ (last visited Sept. 6, 2012).

98. Where an initial HIV drug regimen fails, HAART recommends changing the drug regimen as soon as possible with three new fully effective antiretroviral drugs. HAART states:

> Once virologic failure is confirmed, generally the regimen should be changed as soon as possible to avoid progressive accumulation of resistance mutations.

> Ideally, a new ARV regimen should contain at least two, and preferably three, fully active drugs on the basis of drug treatment history, resistance testing, or new mechanistic class.

99. HAART notes that switching a patient who has experienced failure on one drug combination to different drugs may not be sufficient because a mutation may make HIV resistant to multiple drugs that have similar mechanisms of action. HAART states: "Because of the potential for drug-class cross resistance that reduces drug activity, using a 'new' drug that a patient has not yet taken may not mean that the drug is fully active."

IV. JANSSEN'S PRIOR HISTORY OF ILLEGAL, OFF-LABEL MARKETING

100. Janssen and its parent company, J & J, created fraudulent, off-label marketing schemes that involved three of their largest drugs – Risperdal, Topamax, and Natrecor – at the same time that it orchestrated the off-label marketing of Prezista and Intelence.

101. In 1993, the FDA approved Risperdal to treat schizophrenia. The drug was not tested on the elderly. Nevertheless, Janssen engaged in a fraudulent, off-label marketing campaign promoting the use of the drug to treat dementia in elderly patients. The illegal marketing campaign generated billions of dollars in sales for Janssen and continued despite numerous FDA warning letters concerning the illegal marketing of Risperdal. The illegal marketing campaign only ceased after investigations by the U.S. Attorney's Office in Philadelphia, the New York State Attorney General, the Texas State Attorney General, the California State Attorney General, and the Louisiana State Attorney General resulted in over $4 billion in penalties and settlements.

102. Topamax, a Janssen drug, was approved in 1996 to treat epilepsy and migraine headaches. Janssen developed an extensive program dedicated to the aggressive promotion of Topamax for a laundry list of ailments and diseases– including pediatric bipolar disorder and alcohol addiction – for which it was not indicated and for which it had not received FDA approval. Janssen trained its sales force to mislead physicians into prescribing the drug for off-label uses by

referring to non-existent "scientific evidence" or sometimes to evidence that was significantly scientifically flawed. In April 2010, Janssen pled guilty to violating the FDCA and paid a $6.14 million criminal fine for the illegal promotion of Topamax for psychiatric uses. At the same time, Janssen resolved two whistleblower claims by agreeing to pay $75.37 million for its illegal promotion of Topamax for off-label uses.

103. In 2001, the FDA approved Natrecor for the limited and specific use of intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity. By definition, this condition is an emergency situation that does not occur on a scheduled basis. Another J & J subsidiary, Scios, Inc., developed an unlawful marketing plan around promoting Natrecor for regularly scheduled outpatient infusions. The J & J subsidiary continued the illegal marketing campaign even after convening a panel of 10 cardiologists in 2005 who found that Natrecor should be strictly limited to on-label uses.

104. In October of 2011, the U.S. Justice Department announced that Scios pled guilty to a misdemeanor and agreed to pay an $85 million criminal fine to settle criminal charges related to the marketing of Natrecor for off-label uses.

V. THE FALSE CLAIMS ACT SCHEME

A. Janssen's False and Misleading Messaging in Promoting Prezista

105. In selling and promoting Prezista, Defendant routinely delivered false and misleading messages by:

- promoting Prezista as "lipid-neutral" contrary to its FDA-approved label; and
- overstating Prezista's superiority, efficacy and potency based on the uniqueness of its "binding affinity."

Sections 1 and 2 below explain these two false and misleading messaging campaigns and also give specific examples of oral misrepresentations made to physicians about Prezista.

1. Janssen's Promotion of Prezista as "Lipid-neutral" is a Misrepresentation Which Misleadingly Conceals a Dangerous Side Effect of the Drug

106. Beginning in 2006 and continuing through approximately 2014, Janssen sales representatives and managers have falsely and misleadingly promoted Prezista as "lipid-neutral," meaning that the drug would *not* affect or increase a patient's cholesterol or triglyceride levels, contrary to Prezista's label. This is significant because heart disease caused by high cholesterol and triglycerides is a real threat for AIDS patients. Defendant's promotion of Prezista as "lipid-neutral" is false, it falsely minimizes the threat to patients, and it directly contradicts Prezista's label which in fact shows that Prezista *increases* lipids in patients. Further, the two scientific studies on which Janssen relied are not part of the FDA-approved label and are of questionable scientific value. Janssen was motivated to promote Prezista as lipid-friendly to boost sales and in order to compete with another PI drug, Reyataz, which in fact does *not* have an effect on a patient's lipid levels.

a. Serious Risk of Heart Disease for HIV/AIDS Patients

107. Defendant's off-label promotion of Prezista as "lipid-neutral" misleadingly minimizes the very serious risk of cardiovascular disease for HIV/AIDS patients. With the number of available treatment options, many HIV/AIDS patients are living longer lives and not dying from the HIV/AIDS virus, but rather from cardiovascular events such as heart attack or stroke. In addition to the increased risk of heart problems as patients age, it is thought that HIV/AIDS itself may increase a patient's lipid levels. Also, some HIV/AIDS drugs, in particular PI drugs, increase lipid levels which can lead to heart disease. Further, many PI drugs, including Prezista, are used in combination with the booster drug, Norvir (ritonavir), which is known to increase lipid levels in HIV/AIDS patients.

108. The risk of heart disease caused by high cholesterol is further exacerbated by the fact that cholesterol-lowering drugs may not work for HIV/AIDS patients. That is, high cholesterol caused by boosted PI drugs (such as Prezista boosted with Norvir) may "be refractory to diet, exercise and hypolipidemic drugs." *See* http://hivmanagement.org/pi/html. In other words, patients with high cholesterol caused by their HIV/AIDS drug treatment regimen unfortunately may not be able to lower their cholesterol levels by eating healthier, exercising more or taking cholesterol-lowering drugs.

109. By way of background, cholesterol or lipid levels are measured by analyzing a patient's blood for the following:

- high density lipoprotein (HDL or "good" cholesterol);
- low density lipoprotein (LDL or "bad" cholesterol);
- total cholesterol; and
- triglycerides

110. Cholesterol and triglycerides are two forms of lipids or fatty deposits that circulate in a patient's blood stream. They are necessary for building healthy cells and providing energy for tissues to function. However, high cholesterol (hypercholesterolemia), in particular high LDL cholesterol, or high triglycerides (hypertriglyceridemia) cause heart disease when the fatty deposits clog the patient's arteries. This makes it difficult for blood to flow through the arteries and may lead to a heart attack, stroke or other serious heart condition.

b. Janssen's Promotion of Prezista as "Lipid-neutral" is Contradicted by Prezista's Label

111. Defendant's marketing of Prezista as "lipid-neutral" is directly contradicted by the FDA-approved label for Prezista. Prezista's label shows that the drug has a significant negative effect on lipids, including cholesterol and triglycerides. The label specifically lists as serious

adverse drug reactions ("ADRs") the following: high cholesterol (hypercholesterolemia), high triglycerides (hypertriglyceridemia) and an increase in LDL ("bad" cholesterol).

112. The label shows a significant percentage of patients on Prezista whose lipid levels increased *beyond* the safe or optimal levels which are as follows:

- Total Cholesterol – Below 200 mg/dL
- LDL Cholesterol – Below 100 mg/dL
- Triglycerides – Below 150 mg/dL[1]

113. Prezista caused a significant percentage of patients' lipid levels to increase to high or very high. Specifically, of the treatment naïve patients taking Prezista, 24% developed high total cholesterol, 23% developed high LDL cholesterol and 6% developed high triglycerides. *See* Prezista, Full Prescribing Information, Table 6, pg 6. For treatment-experienced patients taking Prezista, the cholesterol profile was worse - 35% of patients developed high total cholesterol, 22% developed high LDL cholesterol and 20% developed high triglycerides. *See* Prezista, Full Prescribing Information, Table 8, pg 7. These results were based on robust clinical studies detailed in the label and discussed more fully below.

114. By contrast, the label for Reyataz, Prezista's chief competitor, does not list high cholesterol as a serious adverse drug reaction. To the contrary, Reyataz's label contains studies that show that Reyataz does not significantly raise cholesterol:

- Study AI424-138 followed patients taking Reyataz 300 mg, ritonavir 100 mg, tenofovir (an NRTI) 300 mg and emtricitabine (an NRTI) 200 mg. After 96 weeks, patients' mean LDL cholesterol increased only 14% from 92 mg/dL (optimal) to 105 mg/dL (near optimal).
- Study AI424-034 followed patients taking Reyataz 400 mg once daily with the fixed-dose combination: lamivudine (NRTI) 150 mg, and zidovudine (an NRTI)

[1] *See* Third Report of the National Cholesterol Education Program Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, *available at*http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm.

300 mg twice daily. After 46 weeks, the study found no increase in mean LDL levels, which stayed constant at 98 mg/dL over the course of the study.

- Study AI424-045 followed patients taking Reyataz 300 mg once daily with ritonavir, tenofovir (an NRTI), and another NRTI. On average, patients experienced a 10% decrease in cholesterol, from 108 to 98.

115. Because Prezista causes high cholesterol, it is at a competitive disadvantage to Reyataz. This in part motivated Defendant to compete by misleadingly claiming that Prezista is lipid-neutral.

c. Janssen Misleadingly Relied on Unsubstantiated Scientific Studies to Claim Prezista is Lipid-neutral

116. Defendant's so-called support for its "lipid-neutral" claims were two scientific studies regarding Prezista's effect on lipids which are not included in, and directly contradicted by, Prezista's label. The two off-label studies were:

- The DART Study: From the beginning of the relevant time period through 2014, sales representatives of Defendant have relied on a study entitled "Similar Changes in Metabolic Parameters of Darunavir [Prezista] and Atazanavir [Reyataz], each Co-Administered with Low- Dose Ritonavir [Norvir] in Healthy Volunteers (TMC114-C159)" (the "DART Study") in selling and promoting Prezista to physicians.

- The Metabolik Study: Starting in 2010 and continuing until 2014, sales representatives have relied on a study entitled, "METABOLIK (Metabolic Evaluation in Treatment-naives Assessing the Impact of Two Boosted Protease Inhibitors on Lipids and Other Markers): Comparison of the Metabolic Effects of Darunavir/ritonavir [Prezista/Norvir] versus Atazanavir/ritonavir [Reyataz] over 12 weeks" (the "Metabolik Study") in selling and promoting Prezista to physicians.

117. The DART and Metabolik Studies (hereinafter "Lipid Studies") purported to show that Prezista does not cause high cholesterol and/or high triglycerides and that Prezista is comparable to Reyataz in terms of its neutral or minimal effect on lipids.

118. Defendant engaged in off-label marketing of Prezista by downplaying the drug's dangerous effects on total cholesterol and LDL cholesterol, misrepresenting that Prezista was lipid neutral like Reyataz and using the FDA unapproved Lipid Studies to support those contentions.

119. Sales representatives presented and distributed the Metabolik study to physicians. The Metabolik study followed only 65 HIV-infected people over a 12-week period and found similar changes in cholesterol for persons taking Prezista and Norvir on the one hand and Reyataz and Norvir on the other. The study concluded:

> Given its favorable metabolic profile and efficacy in HIV-1-infected subjects DRV/r (Prezista and Retonovir) is a valuable therapeutic option for treatment-naïve subjects and may minimize the risk of metabolic complications.
>
> Changes in metabolic parameters and biomarkers form baseline to Week 12 were comparable for DRV/r and ATV/r-based therapy; longer-term follow-up of these parameters is planned.

120. Janssen sales representatives used this study to market Prezista as a lipid neutral PI. This marketing message was false and misleading because it was contradicted by the phase III clinical trials contained on Prezista's label. Further, the study was of short duration and two of the authors were Tibotec employees at the time the study was released. Further, Tibotec funded the Metabolik Study.

121. A subsequent article discussing 48-week results of the Metabolik Study[2] acknowledged the limited value of even the 48-week results. Referring to the Metabolik Study as a "pilot study" intended to be "an exploratory analysis," it states that "the small sample size and short duration of this trial limit clinical interpretation of these data." *Id.* at 9.

122. Further, sales representatives used the DART Study in selling and promoting Prezista to physicians. The DART study involved only 49 patients – all of whom were *healthy* and not infected with HIV. Seven of the eight authors of the study were associated with Tibotec (now known as Janssen, a J&J subsidiary) at the time of the study.

[2] Aberg, Judith A. et al., "Metabolic Effects of Darunavir/Ritonavir Versus Atazanavir/Ritonavir in Treatment-Naïve, HIV Type 1-Infected Subjects over 48 Weeks", AIDS Research and Human Retroviruses, Vol. 28, No. 00, 2012.

123. Both of these studies are directly contradicted by Prezista's label. Marketing Prezista as "lipid-neutral" is false and misleading because it is contradicted by the more robust, longer term, phase III clinical trials on HIV-infected patients contained in Prezista's label, as opposed to, for example, the DART study conducted on healthy individuals. The label contains evidence of efficacy based on two randomized, controlled studies comparing the safety and effectiveness of a Prezista-ritonavir combination with another PI drug combination (Kaletra-ritonavir). The one study in the label involved 192-week data from 689 patients infected with HIV and the other study involved 96-week data from 595 HIV- infected patients. In both of these studies, a clear majority of patients experienced virologic success on the Prezista-ritonavir combination, however, as noted above, *a significant percentage of patients' lipid levels increased to high or very high*.

d. <u>Janssen Made Misleading Statements About the Results of the Lipid Studies</u>

124. Despite the limited value of the scientific studies, Defendant's sales representatives and managers relied on them and made false and exaggerated statements about the results of these Lipid Studies. Relators personally heard or learned of the following misrepresentations being made to physicians by Defendant's sales representatives on sales calls:

- Prezista is lipid neutral just like Reyataz. You will not get increase of cholesterol levels.
- Using Prezista does not affect lipids just like Reyataz.
- Patients will not see an increase in cholesterol with the use of Prezista. It is lipid neutral so it will not have an effect on cholesterol in the patient. You can expect to see the same cholesterol levels the patient had before treatment while on treatment with Prezista.
- Patients should not see any cholesterol issues whatsoever.
- Your patients all eat like crap anyway so I'm sure they already have high cholesterol so why not choose a drug that won't make matters worse?

- Older PIs are known for increasing lipids and contributing to cardiovascular disease, with Prezista you don't have to worry about that.
- Patients have many risk factors that contribute to heart disease; you don't need a drug to add to the complications. By using Prezista, as shown in the DART Study, you don't have to add high cholesterol to that risk list for patients.
- HIV itself causes high cholesterol, no reason to choose a drug that also does so.
- If healthy patients saw no change you can expect to see the same results in HIV infected patients. If the drug is the culprit it would have occurred regardless of HIV status.
- Patients can expect to see only minimal increases in cholesterol levels based on this [DART] study.
- Pharmacokinetics ("PK") of the drugs prove that Reyataz increases [the effects of] Ritonavir (Norvir) [which increases lipids] and Prezista lowers it.

125. Some of the sales calls at which Relators heard or learned of these misrepresentations are detailed below in Section VI. B. 1.

2. <u>Janssen's Overstated Claims of Superiority, Efficacy and Potency of Prezista Based on Binding Affinity</u>

126. In addition to misleadingly promoting Prezista as lipid-neutral, beginning in and around February 2007 and continuing through the present, Defendant's sales representatives and managers have made unsupported claims regarding Prezista's superiority, efficacy and potency based on its purported superior "binding affinity." All drugs in the PI class of drugs work by binding to the active site of the HIV protease (an enzyme critical for viral replication) and inhibiting it, thus preventing HIV from replicating. However, Defendant's claims of superior binding affinity are misleadingly based on a clinical study of limited scientific value which is not included in the drug's FDA-approved labeling. Further, Defendant's employees falsely and misleadingly characterized the results of the study during sales calls, dinner programs and speaker programs. This binding affinity data was provided to promotional speakers in order to encourage the differentiation of Prezista and Reyataz.

127. Janssen misleadingly relied on an unsubstantiated study to claim superiority, efficacy and potency of Prezista. The study is entitled "Binding Kinetics of Protease Inhibitors to Wild-Type and Multi-Drug Resistant HIV-1 Proteases: A mechanistic study of the genetic barrier to resistance of Darunavir" (hereinafter the "Binding Study") and it was first presented (in poster format) at the 14th Conference on Retrovirus and Opportunistic Infections in Los Angeles, California on February 25-28, 2007. The Binding Study purported to compare Prezista to other PI drugs (Aptivus, Agenerase, Reyataz and Kaletra) and claimed to prove that Prezista's superior "binding affinity," or ability of the drug to bind to the active site of the HIV protease, prevented the virus from mutating. Thus, the drug supposedly was more efficacious and potent than the other PI drugs.

128. The study is not included in the FDA-approved labeling for the drug. Its scientific value is questionable, as Tibotec (now Janssen) not only funded the study, but also provided the scientists who conducted it. Further, the study was performed in the lab, and not on HIV-infected patients.

129. In and around 2007-2008, Nancy Bartnett, a Key Account Manager, and Tony Dolisi, a Manager of New York District 1, had told the Defendant's sales force that the FDA had instructed Janssen to remove any binding affinity claims from early promotional material. To get around this and promote Prezista's binding affinity, Janssen devised a scheme involving medical information requests ("MIRs"), knowing that in certain circumstances, pharmaceutical companies may distribute off-label information to doctors in response to *unsolicited* MIRs. Thus, during national sales meetings, Donna Graham, Sales Training Manager, and the Sales Training Department including Ron Martin, Head of Training, and Mike Iacobellis, National Sales Training

Director, instructed the sales force to proactively request that doctors submit MIRs and make it appear such submissions were unsolicited.

130. To ensure that the off-label binding affinity and other off-label messages were widely disseminated, Janssen developed metrics to measure the volume of MIRs that were forwarded by the sales force to Janssen's clinical medical department, the Janssen department responsible for responding to MIRs. Sales persons, such as Relator Penelow, were reprimanded if their doctors did not submit a sufficient number of MIRs. Because of this fear tactic by Janssen, many sales representatives forged MIRs to avoid a poor performance review.

131. These "fake" MIRs were not limited to requesting off-label information on Prezista's binding affinity. They included requests for other off-label information alleged herein such as once-daily Intelence and Prezista's effect on lipids.

132. In addition, Janssen has continued to emphasize binding affinity as a selling point in more recent years. For example, at a dinner program on March 11, 2014 in Syosset, NY, Janssen-paid speaker, Dr. David Rubin, delivered the latest promotional slide deck being used by Janssen speakers nationwide in promotion Prezista to health care providers. One of the slides specifically overstates Prezista's efficacy by emphasizing how it "tightly binds to HIV-1 protease" and noting its "[e]nhanced binding affinity and its "high binding affinity." These statements are misleading because the five clinical studies cited supposedly in support are of limited scientific value and not included in the drug's FDA-approved labeling. The studies include the Binding Study, discussed above, and four other studies which are problematic in that they are funded/conducted by the Company, lacking in robust clinical significance, flawed trial design and/or their results do not support the statements.

133. Further, in September 2015, at a national Plan of Action meeting held in Philadelphia, Janssen upper management instructed the sales representatives to continue to promote Prezista based on its superior binding affinity. In attendance were the sales representatives from approximately six districts from the Eastern region for Janssen's HIV Division. The POA meeting for the Western region was held simultaneously in Atlanta, GA with the same content and direction. The upper management presenting the materials included: James Cofoni, Product Manager and Meg Anderson, Director of Marketing. While the focus of the meeting was on Janssen's new ARV drug, Prezcobix, this drug is merely a combination of Prezista and a booster drug called Cobicistat. Prezista is still being promoted as a single drug and it was understood that any selling points for Prezcobix which also applied to Prezista, should be used for Prezista. Thus, part of Mr. Cofoni's presentation included a PowerPoint on Prezcobix's binding affinity which was understood to apply to promoting Prezista alone. The information presented misleadingly touted Prezcobix's binding affinity by relying on many of the same problematic, scientifically questionable studies cited in the promotional slide deck discussed above.

a. <u>The Significance of Janssen's Misleading Promotion of Prezista</u>

134. To understand the significance of this off-label promotion, a brief explanation of HIV/AIDS treatment is helpful. For many conditions or diseases, the patient takes one drug to adequately treat or manage the condition. For HIV/AIDS, the recommended treatment regimen is a combination of drugs because the virus is capable of changing or mutating. Fortunately, there are a whole host of ARV drugs in various classes to choose from as treatment options. A "cocktail" of three or more ARV drugs at once can suppress the virus. However, if a patient's disease is not controlled by ARV drugs, the virus may mutate and the patient may develop drug resistance. Drug resistance is when a drug no longer works to fight the virus because the virus has mutated. In addition, the patient may be resistant to other drugs (even those which the patient has not yet taken

may be knocked out as potential treatment options) if the virus mutates. When a patient develops resistance to one or more drugs (or an entire class of drugs), the physician must determine which drugs are still available and will still work for the patient. There are various drug-resistance tests the physician can use to help determine the patient's remaining treatment options. The real risk involved in drug resistance is treatment failure; that is, when a patient runs out of available drugs that will work to fight the virus. *See* http://www.aids.org/topics/hiv-resistance-testing/

135. Thus, claims that Prezista is a stronger drug with superior binding affinity that would prevent the virus from mutating is very important to physicians deciding which drugs to prescribe. This promotion instilled a false sense of protection that the patient would not become resistant to Prezista and the drug would continue to be effective in fighting the AIDS virus. By claiming that high binding affinity reduced the likelihood that HIV mutations would cause the drug to fail, doctors and patients were given the false illusion that Prezista would minimize chances for drug failure. This induced doctors to (1) prescribe Prezista over other PIs for treatment naive patients (patients who had not yet taken any ARV drugs) and (2) prescribe Prezista to experienced patients (patients who had already taken ARV drugs) where other PIs failed instead of switching these patients to another class of HIV drugs. In both cases, physicians' medical judgments were influenced by Janssen's false statements.

136. If a patient has an HIV strain that is resistant to one drug in a three drug cocktail, it is more likely that a patient will become resistant to the other two drugs. HIV is more capable of mutating to develop resistance to two active drugs than three active drugs. By providing false assurances that HIV would not mutate to become resistant to Prezista, Janssen increased the likelihood that doctors would prescribe Prezista when it did not work, thereby increasing the likelihood that a patient's HIV would become resistant to multiple HIV drugs.

b. Janssen Made Misleading Statements About Prezista's Binding Affinity

137. Janssen routinely overstated the results of the scientifically questionable Binding Study such as Prezista's superiority to other PI drugs, its efficacy, strength, potency and durability. In promoting Prezista to physicians, Janssen sales representatives and mangers made unsupported representations to physicians such as the following:

- Prezista is more effective than other PIs.
- On Prezista, the patient is less likely to fail due to HIV mutations.
- Prezista can be used when patient has failed on other PIs.
- Patients won't fail on Prezista because of its binding affinity.
- Prezista's binding affinity makes it the best PI on the market.
- Prezista is the most efficacious and durable PI because of its binding affinity.
- The binding affinity puts Prezista in a class by itself. It's different from every other PI.
- Prezista stays "in the pocket" (of the HIV protease active site) leading one to believe it's a stronger, tighter binding to the receptor and therefore better for the patient so they would be less likely to fail. (Sales representatives used a visual representation to demonstrate this point by taking a fist and closing the other hand around the fist.)

Relators heard Janssen representatives make the above statements to doctors and attended internal sales meetings where they were told to make such statements and give the visual representation set forth above.

3. Janssen's Sales of Prezista Increased Significantly as a Result of the Off-Label Marketing Campaign

138. Prezista sales increased significantly as a result of Defendant's off-label marketing campaign. As shown in the chart below, according to J & J's Annual Reports, Prezista's worldwide sales increased significantly from $592 million in 2009 to over $1.8 billion in 2014:

Prezista Sales:

Year	Approximate Sales
2009	$592,000,000
2010	$857,000,000
2011	$1,211,000,000
2012	$1,414,000,000
2013	$1,673,000,000
2014	$1,831,000,000

B. Off-label Marketing of Intelence

1. Intelence's Limited FDA-Approved Label Placed It at a Competitive Disadvantage

139. Intelence is an NNRTI drug that was approved in 2008 for twice a day use in treatment-experienced patients. Specifically, with respect to indications and usage, the label states Intelence is "indicated for treatment of HIV-1 infection in *treatment-experienced* patients 6 years of age and older with viral strains resistant to an NNRTI and other antiretroviral agents." (Emphasis added). And with respect to dosing, the label states: "Adult patients: 200 mg (one 200 mg tablet or two 100 mg tablets) taken *twice daily* following a meal." (Emphasis added). Contrary to the label, Defendant, starting at launch in 2008 and continuing through 2014, promoted and marketed the drug to be used once-daily and also for treatment-naïve patients.

140. If Intelence were to be lawfully promoted and marketed in accordance with its FDA-approved label, it would only be promoted to be prescribed to a limited group of patients – those willing and able to comply with a twice-daily drug regimen and those who were treatment-experienced in that they had "viral strains resistant to an NNRTI and other antiretroviral agents." In order to increase sales and compete with other NNRTI drugs with more expansive FDA-approved indications, Janssen engaged in an off-label marketing scheme.

141. The fact that Intelence is approved for twice daily use places it at a competitive disadvantage with ARV drugs that have been approved for once a day use. For example, Bristol-

Myers Squibb's NNRTI, Sustiva (efavirenz), is approved to be used once a day when taken with other antiretrovirals. Doctors recognize that patients are more likely to comply with a simplified medication regime that must be taken only once a day.

142. In fact, the label for Intelence specifically warns against doubling the dose of Intelence if a patient misses a pill by more than 6 hours. The label states:

> **If you miss a dose of INTELENCE® by more than 6 hours of the time you usually take it, wait and then take the next dose of INTELENCE® at the regularly scheduled time.**
>
> **Do not take more than your prescribed dose to make up for a missed dose.**

(Emphasis added). Despite this specific warning, Janssen's off-label promotion recommended doubling the dose and taking at one time each day.

143. Moreover, the fact that Intelence is only approved for treatment-naive patients limits the drugs' potential market share, reducing its potential profitability.

2. Janssen Fraudulently Marketed Intelence for Once a Day Use

144. Beginning in 2008 and continuing through 2014, Janssen made false and misleading statements about the safety and efficacy of using Intelence once a day.

145. Janssen sales representatives and managers often used anecdotal evidence from individual doctors and small studies in making claims that Intelence was safe and effective for once-daily use.

146. For example, sales representatives touted a small study, funded by Tibotec (now Janssen), to support their off-label promotion of once-daily dosing of Intelence. *See* DeJesus et al., *Pharmacokinetics of Once-Daily Etravirine (ETR) Without and With Once-Daily Darunavir/Ritonavir (DRV/r) in Antiretroviral-Naïve HIV-1 Infected Adults, Antiviral Therapy,* 2010 15:711-720 (the "DeJesus Study"). The DeJesus Study involved only 23 patients with HIV

who switched from taking Intelence twice-daily to taking Intelence once-daily. After only six weeks, the study reported no significant increase in HIV viral load. According to its conclusion, the small, short study merely provided support for further investigation of once-daily Intelence. However, contrary to the approved Intelence label providing for twice-daily dosing, the results of the DeJesus Study were used and promoted on sales calls by representatives and managers in support of Intelence once a day. Further, the Study was conducted by DeJesus, a National Promotional Speaker for Tibotec and two Tibotec scientists, among others.

147. Further, Janssen instructed sales representatives to emphasize that due to Intelence's long half-life (the time the drug remains in a patient's body), Intelence would still be effective in fighting the virus even if taken only once daily instead of twice.

148. This once-daily promotion was contrary to the FDA-approved dosing instructions on the label and not supported by the clinical trials supporting the label. According to the FDA Office Director memo, dose selection of Intelence in Phase III clinical trials was based on two Phase II clinical trials, TMC-125-C203 and TMC-125-C223. Both of these Phase II trials studied different doses of Intelence taken twice daily, but did not study the efficacy and safety of Intelence when taken once daily.

149. Despite the lack of evidence demonstrating that Intelence was safe and effective when used once a day, Janssen marketed doctors to prescribe 400mg of Intelence once a day.

150. With respect to sales calls with doctors, Relator witnessed Ms. Bartnett and Tim McSherry (Sales Trainer) make the following statement regarding Intelence:

- Intelence can be used QD due to its long half-life [the rate that Intelence leaves the body].
- Intelence has been tested with QD use and patients did great! …but Janssen doesn't want to put the money behind going for a QD indication because they are launching another QD NNRTI - Edurant.

- Intelence QD can be used for dosing symmetry with the fixed dose NRTIs.
- You can start a patient on BID Intelence and once you feel comfortable they are stable, switch the patient to QD to make it easier, there are studies that have been done that are not in our package insert showing these patients did fine.

151. Doctors and physician assistants responded positively to the message:

- John Weber PA at Beth Israel Medical Center stated: Great to know, I would love to use it QD for ease of use.
- Dr. Christopher Busillo at NYU Downtown - HIV Clinic (170 William St., Manhattan) stated: I will [prescribe QD] if you think the patients will stay undetectable.
- Dr. Donald Kaminsky stated: Intelence is the best drug you guys have, thanks for the half-life info I now will use it QD.

3. Janssen Fraudulently Marketed Intelence for Use In Treatment-Naïve Patients Contradicting the FDA-Approved Label for Use in Only Treatment-Experienced Patients

152. Janssen made false and misleading statements about the safety and efficacy of prescribing Intelence to treatment- naïve patients. Janssen sales representatives and managers used a number of different approaches in promoting Intelence for use in treatment-naives contrary to the label.

153. For example, Defendant used the DeJesus Study, discussed above, a small, not scientifically valid study to support their off-label promotion. This Study only involved 23 patients over 6 weeks and was not clinically significant. Further, it was funded by and conducted in part by Tibotec. Nevertheless, Janssen's sales force used this study to support prescribing Intelence to treatment-naive patients.

154. Further, with respect to sales calls with doctors, Relators both witnessed, on multiple occasions, Nancy Bartnett (Key Account Manager), Tony Dolisi (Manager of New York District 1), Tim McSherry and Jimmy Kwok (Senior Virology Sales Representative) make the following false statements regarding Intelence to doctors:

- It was safe and effective to prescribe once-a-day Intelence in combination with a three or four drug cocktail that included Prezista to treatment-naive patients. (Typically, patients are prescribed a three-drug cocktail that mix and match different classes of HIV medication. Prezista is a PI and is often prescribed with two NRTIs to treat HIV. Contrary to its label, Defendant marketed Intelence for treatment-naive patients to be used in a four drug cocktail that included Prezista and two NRTIs. These sales persons falsely told doctors prescribing Intelence in such a four drug cocktail could only help and would not hurt treatment-naive patients.)

- It was safe and effective to prescribe Intelence to treatment-naive patients who tested positive for HIV with a k103M mutation. Defendant claimed that Intelence was effective against this mutated strain of HIV while other NNRTIs were not. In reality, there were superior once-a-day treatment options for patients with the k103M mutations that were approved and recommended for treatment naïve patients.

155. In reality, as discussed above, it was not safe and effective to prescribe Intelence in this manner and potentially harmful.

156. Janssen's off-label promotion of Intelence for use in treatment-naïve patients potentially harmed these patients. One of the goals in selecting antiviral medications for treatment-naive HIV patients is to maximize future treatment options if their medication fails. A virus that develops resistance to a powerful HIV drug may also likely be resistant to less powerful HIV drugs. Thus, HIV cocktails are administered in a sequence to give a patient the maximum number of future options if their current medication fails.

157. Consequently, the DHHS Guidelines recommend only certain antiviral drugs for treatment-naive patients. The DHHS Guidelines **do not** recommend Intelence for treatment-naive patients. According to Intelence's label, if a patient develops resistance to Intelence, they will also likely develop resistance to the following antivirals: delavirdine, efavirenz, and/or nevirapine.

158. Moreover, another factor when choosing which HIV medication for treatment-naive patients is the likelihood that a patient will comply with a doctor's dosing instructions. As discussed above, patients are more likely to adhere to a once-a-day dosing regimen than a twice a

day dosing regimen. If patients to do not take antiviral medication as prescribed and miss doses, they are more likely to develop resistant strains of HIV. Consequently, by promoting Intelence to treatment-naive patients, Janssen was advocating a more complicated drug regiment than a once-a-day cocktail that is often prescribed to treatment-naive patients – thereby increasing the likelihood of non-compliance and drug failure.

159. Defendant promoted Intelence for off-label uses from the time of its launch in 2008, continuing through September 2014. As shown in the chart below, and based on J & J's Annual Reports, Janssen's Intelence worldwide sales have been driven upward by Defendant's fraudulently marketing the drug for off-label uses:

Intelence Sales:

Year	Approximate Sales
2010	$243,000,000
2011	$314,000,000
2012	$349,000,000
2013	$379,000,000

VI. JANSSEN'S MISLEADING AND OFF-LABEL MESSAGING WAS DELIVERED NATIONWIDE

A. Janssen's Nationwide Sales Force was Instructed to Market Off-Label

160. The off-label marketing of Prezista and Intelence was widespread. Janssen has approximately seventy-nine sales representatives in twelve districts across the United States (New York 1, New York 2, New England, Mid-Atlantic, Chesapeake, Midwest, Florida, Mid-South, Pacific South, Pacific North, Southeast and Southwest) who market Prezista and Intelence.

161. The nationwide sales force was instructed on how to market off-label by Janssen during "pod calls," "district calls," "district meetings," "triad meetings," and "Plan of Action" meetings ("POAs").

Pod Calls

162. On pod calls, two Key Account Managers ("KAMs") from different districts would conduct a talk with approximately 10-15 sales representatives from across the country. These calls were held once a month. Off-label marketing was encouraged on these calls and sales persons in different districts shared tips on how to off-label market Intelence and Prezista, including the off-label marketing schemes detailed above.

163. Relators participated in many monthly pod calls on which off-label marketing of Prezista and Intelence was discussed. On the calls, many individuals relayed off-label sales tactics, including promoting Prezista as lipid-neutral. Further, Relator Penelow's notes mention that she should contact KAM Nancy Bartnett to get the off-label Binding Study and Lipid Studies to use in the field.

164. Relators and their respective "pod" groups each attended a special meeting at Janssen headquarters in New Jersey with upper-level management. Relator Brancaccio's pod group attended in the Fall of 2010 and Relator Penelow's group in August of 2011. At both meetings, Janssen (formerly Tibotec) upper management, including the President, was in attendance and participated in the discussion. The purpose of the meeting was to discuss with the high-level management what sales strategies were working in the field and how customers were responding. At Relator Penelow's meeting, off-label marketing strategies were discussed. Included at the meeting, among others, was the President, VP of Marketing, VP of Sales, VP of Key Account Managers, VP of Human Resources, VP of Communications and the VP of Clinical.

District Calls

165. District calls, which took place on average 2-4 times a month, were led by district managers and included all the salespeople in a district. Manager of New York District 1, Tony

Dolisi, led these calls in Relator Penelow's district and encouraged the sales force to promote the off-label marketing messages detailed herein.

District Meetings

166. District meetings, which took place approximately 8-10 times a year, were in-person meetings led by district managers and included all the sales representatives in the district. Off-label promotion of Prezista and Intelence was often discussed, including the use of off-label studies. After these district meetings, sales representatives would receive the off-label study and use it on sales calls with providers. Some sales persons were given many copies by Defendant. Sales representatives all comprehended that the studies should be disseminated like a sales promotion piece. In order to disguise the off-label marketing, binders were provided with "For educational purposes only" stamped across the posters that were in the binders.

167. Relators recall that to encourage off-label marketing of Intelence, the sales force was told that Janssen did try to get QD (once a day) approval of Intelence from the FDA, but they didn't have enough data to support approval. Upper management told sales representatives that they would ultimately receive QD approval for Intelence as the trials continued. They assured sales persons that they need not worry about the indication, that they should promote QD dosing, that the long half-life of Intelence supported QD dosing, and the sales representatives could share this information with physicians. Marketing slides were shown to sales representatives that discussed the long half-life of Intelence. Janssen made it clear at all district meetings that it wanted the sales representatives to share this data with health care professionals, including physicians, physician assistants, and nurse practitioners. The message was that Intelence could be prescribed once-a-day because of its long half-life.

168. Manager Dolisi presented at multiple district meetings throughout the relevant time period and stated that Janssen's intention with Intelence was to promote off-label once-a-day

Intelence immediately because Janssen needed to increase Intelence sales in the short-term because many new QD regimens were soon coming to market. Dolisi is no longer employed at Janssen. He left their employ in approximately August 2015 and currently works for Turing Pharmaceuticals.

169. The sales force was pressured to push hard when selling Intelence. Janssen hoped to cause health care professionals to issue as many Intelence prescriptions as possible in whatever manner necessary. Using this direction from upper management, Dolisi (and other district managers) pressured and intimidated the sales force to use off label studies to increase sales revenue from 2008 through 2014.

POA Meetings

170. Each year, the virology sales force would be presented with a Plan of Action, which was a marketing plan distributed to the national sales force. The Plan of Action would be discussed in meetings called "POAs", in which the entire virology sales force, the national sales director, the marketing team, the medical science liaison and community liaisons all attended. Upper level executives at Janssen continued to instruct the Janssen sales force to market off-label at POAs.

171. Janssen announced in or around 2009 at a Nationwide POA meeting that it had attempted to obtain approval for once-daily Intelence a second time and that the FDA had requested long, expensive, time consuming clinical trials. Janssen stated they would not be pursuing these trials both because of the cost, and because Janssen was on the verge of launching Complera, another QD HIV regimen option. Janssen did not want Intelence to compete with Complera, which was eventually approved by the FDA in 2011. These comments were stated by upper management to the entire national sales team.

172. At that point, most sale representatives had already been successfully promoting QD Intelence off-label. Janssen had already made ample profits from its illegal conduct and

exceeded sales goals. The business plan for Intelence, presented by Dolisi, had been for Janssen to "get in," make their millions, and get out. Janssen executed that plan by using the illegal marketing campaign described herein through September 2014, when Janssen stopped marketing Intelence.

173. At the 2015 POA, the sales force was provided with slides that instructed the sales force on how to promote Prezista's superior binding affinity. These slides were presented by a Janssen executive at the POA, see discussion above in Section V.A.2.

174. Additionally, at POAs, Relators were provided off-label studies and posters in-between formal talks and presentations. These materials were usually provided during breakout sessions at the POA meetings. These studies included the ones described herein to promote Prezista and Intelence off label.

Trial Meetings

175. Triad meetings were more informal gatherings of members of the sales force within a district that frequently took place in restaurants. Relator Penelow was repeatedly urged to market off-label at these triad meetings by Dolisi and Bartnett.

176. Through these calls and meetings, Janssen instructed its nationwide sales force to market Prezista and Intelence off-label.

177. Relator Penelow has talked to ten current employees who have been pressured to market off-label and have in fact marketed Prezista and Intelence off-label. These sales persons marketed in New Jersey, New York, Florida, Washington DC, Maine, and California. Relator has also talked to four former employees who left Janssen because they were pressured to market Prezista and Intelence off-label and were threatened to be placed on a performance plan, requiring them to meet certain metrics or else be dismissed. These persons - Russ Moyer, Lisa Cruz, Joe Holshoe and Donna Graham - were top sellers at Janssen. Joe Holshoe worked as a Senior

Virology Sales Representative for Janssen covering New Hampshire, but left the company when he was pressured to market off-label. He now lives in Rhode Island and works for the Navy.

178. Only sales representatives who engaged in off-label marketing were more likely to meet aggressive sales targets set by Janssen. These employees, who met or exceeded their sales targets, were rewarded with promotions, bonuses and other prizes that included fully-paid vacations. One such Janssen sales representative, Yvonne Wind-Vasquez, who also worked as a prescribing Physician's Assistant in Florida, has received numerous sales bonuses, extravagant trips and gifts for producing high sales figures, all while continuing to work in an HIV practice prescribing HIV medication. Janssen ignored this conflict of interest. Ms. Wind-Vasquez and her prescribing partners have maintained the highest market share in the country. Her Janssen manager, Scott Libby, has been promoted to a director's position, and has arranged to have Janssen geographically realign sales districts in order to maximize bonus dollars. In accordance with his demands, Florida is now considered part of the Western region. Conversely, when Relator Penelow failed to meet her sales targets because, *inter alia*, she refused to engage in off-label marketing, she was denied promotions and bonuses.

B. Janssen Delivered the Misleading Messaging During Sales Calls, Dinner Programs and Speaker Programs

1. Sales Calls on Physicians

179. Janssen pressured its sale representatives to engage in off-label marketing in face to face meetings with doctors. Janssen gave sales representatives multiple copies of study summaries to distribute to doctors that contained off-label claims. As set forth in detail below, sales representatives were instructed by their supervisors to use these studies to make false and misleading claims about Intelence and Prezista. To cover their tracks, the sales representatives

were told not to leave these summaries with doctors, but to retrieve them after they showed them to doctors. As sales representatives, Relators have firsthand knowledge of these facts.

180. For example, Relator Penelow was given a binder by Sales Trainer, McSherry, with studies that purportedly supported the use of Prezista and Intelence for off-label use. Bartnett and McSherry encouraged Relator Penelow to use this binder, insisting that sales persons all around the county were using a similar binder.

181. Relators Penelow and Brancaccio both experienced off-label promotion in sales calls with Bartnett, McSherry and Dolisi. Each would explain very clearly to the provider that Intelence is approved for only twice-a-day use because Janssen did not want to spend money to obtain approval for once daily dosing. These sales persons and managers told doctors that Intelence was safe and effective for once a day use and, if it were not for the cost of further clinical studies, Janssen would have sought and received such approval. Moreover, these sales persons and managers told doctors that Intelence was safe and effective for once-a-day use as well as for treatment-naïve patients.

182. In one instance, Bartnett made Relator Penelow repeat Janssen's standard off-label marketing pitch to a doctor, despite Penelow's stated reluctance to do so. Bartnett listened approvingly as Relator Penelow told a doctor that Intelence had a long half-life, was safe and effective for once-daily use, and that if Janssen decided to spend the money, they could receive approval for once-daily Intelence.

183. Janssen's misleading messages regarding Prezista were delivered on in person sales calls, including those involving the following Janssen sales representatives/ managers and physicians:

- Key Account Manager ("KAM") Bartnett called on Drs. Sanjana Koshy MD, Tessa Gomez MD, John Weber PA, Nadim Salomon MD at Beth Israel Medical Center -

Peter Kruger HIV Clinic (317 E. 17th St., Manhattan) whose patients are 100% Medicaid and NY State ADAP.

- KAM Bartnett called on Iris Nagin PA at the Lower East Side Treatment Center (46 E. Broadway, Manhattan) whose patients are 100% Medicaid and NY State ADAP.

- KAM Bartnett called on Larry Landphair PA at Astor Medical Group (67 Irving Place, Manhattan) whose patients have all types of insurance, including Medicaid and NY State ADAP.

- KAM Bartnett and McSherry called on Drs. Lawrence Hitzeman MD, Jean-Louis Salinas MD, Richard Gold MD at Village Care - HIV Clinic & Community Based Organization (121 W. 20th St., Manhattan) whose patients are 100% Medicaid and NY State ADAP.

- KAM Bartnett and McSherry called on Dr. Ricky Hsu MD at his office (154 W 14th St., Manhattan). His patients include those with all types of insurance, including Medicaid and NY State ADAP.

- KAM Bartnett and McSherry called on Drs. Rona Vail MD, Gal Mayer MD, Ward Carpenter MD, and Susan Weiss NP at Callen Lorde Community Health Center - Lesbian/Gay/Bi-Sexual/Transgender HIV Clinic (356 W. 18th St., Manhattan) whose patients are100% Medicaid and NY State ADAP.

- Manager of New York District 1 Dolisi and Jimmy Kwok called on Dr. Andre Brutus MD at Brookdale Hospital (1 Brookdale Plaza, Brooklyn). His patients include those with all types of insurance, including about 80% Medicaid.

- Manager Dolisi called on Dr. Joseph Exilhomme MD of Kings County Hospital (451 Clarkson Ave, Brooklyn). His patients include those with all types of insurance, but mainly Medicaid.

- Manager Dolisi and Jimmy Kwok called on Drs. Samuel Uter MD and Joseph Paul MD at Pierre Toussaint Family Health Center (1110 Eastern Parkway, Brooklyn) whose patients include all types, including Medicare, Medicaid and NY State ADAP.

- KAM Bartnett and Manager Dolisi called on Drs. David Rubin MD and Sorana Segal-Maurer MD at New York Hospital Queens - HIV Clinic (138-47 Horace Harding Expwy, 2nd Fl, Queens) whose patients are 100% Medicaid and NY State ADAP.

- Manager Dolisi and Jimmy Kwok called on Dr. Sangam Jhaveri MD at Queens Long Island Medical Group (18005 Hillside Ave, Queens) whose patients included all types, including Medicare, Medicaid, and NY State ADAP.

- Manager Dolisi and Jimmy Kwok called on Alla Shkolnik NP (42 Hausman St, Brooklyn) whose patients include all types, including Medicare, Medicaid, and NY State ADAP.

- Manager Dolisi and Jimmy Kwok called on Kathleen Aratoon NP (8268 164th St, Queens) whose patients include all types, including Medicare, Medicaid, and NY State ADAP.

- KAM Bartnett called on Dr. Alexander McMeeking MD and Abbe Friedberg NP (110 E. 40th St., Manhattan) whose patients include all types, including Medicare, Medicaid, and NY State ADAP.

- KAM Bartnett called on Dr. Michael Mullen MD, Chief Medical Director at Mt. Sinai - Jack Martin HIV Clinic (5 E. 98th St., Manhattan) whose patients include100% Medicaid and NY State ADAP.

- KAM Bartnett called on Dr. Christopher Busillo at NYU Downtown - HIV Clinic (170 William St., Manhattan) whose patients include about 80% Medicaid and NY State ADAP.

- KAM Bartnett and Manager Dolisi called on Dr. Donald Kaminsky at his office (10 Union Sq. East, Manhattan). His patients include some Medicaid patients.

184. Janssen's misleading messages regarding Intelence were delivered in sales calls, including those involving the following Janssen sales representatives/ managers and physicians:

- KAM Bartnett and McSherry called on Dr. Ricky Hsu at his office (154 W 14th St., Manhattan). His patients include Medicaid and NY State ADAP patient.

- KAM Bartnett and McSherry called on Dr. Rona Vail and Dr. Gal Mayer at the Lorde Community Health Center – Lesbian/Gay/Bi-Sexual/Transgender HIV Clinic (356 W. 18th St., Manhattan). Their patients are all Medicaid and NY State ADAP patients.

- KAM Bartnett called on Dr. Sanjana Koshy, Dr. Tessa Gomez, and Dr. Nadim Salomon at Beth Israel Medical Center - Peter Kruger HIV Clinic (317 E. 17th St., Manhattan). Their patients are Medicaid and NY State ADAP patients.

- Manager Dolisi and Jimmy Kwok called on Dr. Andre Brutus at Brookdale Hospital (1 Brookdale Plaza, Brooklyn). His patients include Medicaid patients.

- Manager Dolisi called on Dr. Joseph Exilhomme at Kings County Hospital (451 Clarkson Ave, Brooklyn). His patients include Medicaid patients.

- Manager Dolisi and Jimmy Kwok called on Drs. Samuel Uter MD and Joseph Paul MD at Pierre Toussaint Family Health Center (1110 Eastern Parkway, Brooklyn). Their patients include Medicare, Medicaid, and NY State ADAP patients.

- KAM Bartnett and manager Dolisi called on Dr. David Rubin and Sorana Segal-Maurer at New York Hospital Queens - HIV Clinic (138-47 Horace Harding Expwy, 2nd Fl, Queens). Their patients are Medicaid and NY State ADAP patients.

- Manager Dolisi and Jimmy Kwok called on Sangam Jhaveri MD at Queens Long Island Medical Group (18005 Hillside Ave, Queens). His patients include Medicare, Medicaid, and NY State ADAP.

- KAM Bartnett called on Donald Kaminsky MD at his private practice (10 Union Sq. East, Manhattan). His patients include Medicaid patients.

- KAM Bartnett, Jimmy Kwok, and Christine Brancaccio called on Dr. Carlos Salama at Elmhurst Hospital (79-01 Broadway, Elmhurst). His patients are predominantly Medicare, Medicaid and NYS ADAP.

185. For physician sales calls, Janssen gave its sales representatives copies of the studies to rely on when calling on physicians, even though the studies are not included in the drug's package insert, approved by the FDA and are of questionable scientific value. Managers and supervisors pressured the sales force to show these studies to doctors to promote Intelence and Prezista off-label. The sales force, including Relators, was specifically instructed not to follow official company policy that disallowed the distribution of these studies to doctors. For example, Dolisi (manager) and Bartnett (KAM), Relators' direct supervisors, provided Relators the studies referenced herein and encouraged Relators to discuss these studies with doctors.

186. Furthermore, in around March 2012, Dolisi told his sales force to "be creative outside the label" when marketing Prezista and Intelence.

187. In fact, when doctors had scientific and medical questions about Prezista and Intelence, the sales force, including Relators, were instructed by Bartnett not to route calls to Janssen's scientific liaison, but rather to Bartnett herself, who would falsely claim that she was the scientific liaison and repeat the false and misleading marketing messages.

188. Within Relators' district (NY 1), Bartnett and Dolisi freely used the studies during sales calls to physicians. They frequently showed the studies to physicians, sometimes leaving the studies at the physicians' offices, and sometimes sending them electronically.

189. KAM Bartnett bragged to Relator Penelow about her off-label sales calls in an attempt to convince Relator to do the same. When Relator Penelow voiced her discomfort, she was in turn demoted and taken off key initiatives. KAM Bartnett bragged to Relator Brancaccio that the off-label marketing was making a great impact with and resonating with physicians. To demonstrate, she referenced a physician she routinely called on, Dr. Segal-Maurer, who had a 54% market share of Prezista prescriptions within all ARV drugs, and a 57.5% market share within the PI class.

190. On November 13, 2012, on a sales call on Dr. Glenn Turrett, a physician at New York Hospital Queens, Bartnett falsely minimized the risk of Prezista increasing a patient's lipids. She stated, "from a lipid standpoint, they [Reyataz and Prezista] are both the same" when in fact, as discussed above, this is untrue as Reyataz does not raise cholesterol, as Prezista does.

2. The Kickback Scheme

a. Dinner Programs

191. In addition to sales calls, Janssen fraudulently promoted Prezista off-label at dinner programs by overstating their superiority to other drugs based on their so-called binding affinity and their alleged favorable lipid profile and fraudulently promoted Intelence off-label for once a day use and for treatment naives. These dinner programs initially started as a mere thank you for high volume sellers, but eventually morphed into well-attended educational dinners. Often at expensive and luxurious restaurants, these dinners were fully paid for by Defendant. KAM Bartnett distributed a slide deck for speakers to use at dinner programs that included a slide

reprinting Figure 2 from the Binding Study. Figure 2 purportedly demonstrates in graph form the much stronger binding affinity of Prezista than the other PI drugs included in the study.

192. Oftentimes, Janssen would plant questioners in the audience of these dinner presentations in order to ensure that off-label use of the drugs was a topic of discussion. Some health care provider attendees who asked off-label questions included the following: Dr. Michael Mullen, Dr. Nadim Salomon, Dr. Donald Kaminsky, Dr. Gal Mayer, Larry Higgins and John Weber PA and Mark Miller RN. This tactic disguised that Janssen organized the speaker events for the purpose of engaging in off-label marketing.

193. For example, Sorona Segal-Maurer MD, New York Hospital of Queens, became a national speaker for Intelence (as well as Prezista). She was flown all over the country to do numerous speaking programs on behalf of Tibotec. Before a program began in NY, KAM Bartnett, would ask one of her providers in the audience to ask Dr. Segal-Maurer during the lecture, "Can Intelence be used once a day because of its long half life?" This "plant" opened the conversation for off label discussion. Segal-Maurer is well known for her willingness to "go off the reservation" to get off label information disseminated to her audience.

194. Some of the dinner programs did not even include a formal, promotional speech or presentation given by the paid speaker, but rather the entire program merely amounted to a casual conversation at which dinner was provided for free.

195. Dinner programs were always held at high-end restaurants, such as Morton's, Capital Grille, and Fleming's Steak House, and Relators, throughout their employment, had unlimited expense accounts to fund these programs.

196. Janssen's misleading promotion regarding Prezista concerning the favorable lipid profile and the binding affinity were delivered during the following dinner programs:

- January 27th, 2010 – A dinner program at Bond Street Restaurant in New York, NY featured a promotional speech by Dr. Sorana Segal-Maurer, who was instructed by Key Account Manager Bartnett to sell Prezista on the uniqueness and favorable binding ability of Prezista. Bartnett placed Mark Miller in the audience to bring up questions regarding the off-label uses of the drug during the question and answer session that followed. Attendees included: Bina Berkovich, PA, Dr. Daniel Bowers, Dr. Krisczar Bungay, Key Account Manager Reggie Cadet, Edwin Calderon, PA, District Manager Dolisi, Mohammed Eritonui, Dr. Avisheh Forouzesh, Dr. Stuart Haber, Vanessa Haney, Dr. Joanna Kopacz, Eric Leach, NP, Dr. Paul Mathieu, Dr. Gal Mayer, Sales Trainer McSherry, Mark Miller, RN, Erik Mortensen, NP, Iris Nagin, NP, Dr. Anita Radix, Dr. Joseph Rahimian, Dr. Sireesha Reddy, Access and Reimbursement Director Eric Sherr, Dr. Rashmi Singh, Senior Virology Sales Specialist Steve Smacchia, Dr. Celestine Tchikounzi, Carl Urban, Ph.D., Dr. Rona Vail, Dr. Wehbeh, and Mulubrhan Zewde, NP.

- February 23rd, 2010 – A dinner program at Fleming's Steak House in Raleigh, NC featured a promotional speech by Dr. Segal-Maurer.

- March 30th, 2010 – A dinner program at Joe's Stone Crab in Miami Beach, FL featured a promotional speech by Dr. Segal-Maurer, who promoted information off-label concerning Prezista's binding affinity and effect on lipid levels.

- April 13th, 2010 – A dinner program at Acquarello in San Francisco, CA featured a promotional speech by Dr. Segal-Maurer, who promoted information off-label concerning Prezista's effect on lipid levels.

- April 14th, 2010 – A dinner program at BLD Restaurant in Los Angeles, CA featured a promotional speech by Dr. Segal-Maurer.

- April 14th, 2010 – A dinner program at Cecconi's in West Hollywood, CA featured a promotional speech by Dr. Segal-Maurer.

- May 12th, 2010 – A dinner program at Serenade in Chatham, NJ featured a promotional speech by Dr. Segal-Maurer.

- June 28th, 2010 – A dinner program at Capital Grille in Chicago, IL featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's effect on lipid levels.

- August 10th, 2010 – A dinner program at Steinhilber's Restaurant in Virginia Beach, VA featured a promotional speech by Dr. Segal-Maurer.

- October 7th, 2010 – A dinner program at Porter House in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity. Attendees included: Sherly Altidor, PA, Dr. Lloyd Bailey, Dr. Ronald Grossman, Peter Harz, Thomas Hayden, Geraldine Joseph, PA, Sales Trainer McSherry, Dr. Michael Morelli, Senior Virology Sales

Representative Dennis O'Keeffe, Brad Rothenbuhler, Dr. Antonio Urbina, Keith Wills, PA, Barbara Zagelbaum, Mulubrhan Zewde, NP, and Stuart Zuckerman, RPH.

- November 30th, 2010 – A dinner program at Citrone in Redlands, CA featured a promotional speech by Dr. Segal-Maurer.

- February 1st, 2011 – A dinner program at Aldea Restaurant in New York, NY featured a promotional speech by Dr. Seagl-Maurer who promoted information off-label concerning Prezista's effect on lipid levels. Attendees included: KAM Ms. Bartnett, Dr. Robert Chavez, District Manager Dolisi, Dr. Michael Gaisa, Dr. Jeffrey Greene, Dr. Lawrence Hitzeman, Dr. Donald Kaminsky, Dr. Martin Markowitz, Dr. Alexander McMeeking, Sales Trainer McSherry, Dr. Michael Mullen, Relator Jessica Penelow, Dr. Jean-Louis Salinas, and Senior Virology Sales Specialist Steve Smacchia.

- May 4th, 2011 – A dinner program at Carltun on the Park in East Meadow, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity, stating that it staying in the pocket longer than any other PI drug, and effect on lipid levels, favorably comparing it to Reyataz. Attendees included: KAM Bartnett, Relator Christine Brancaccio, John Civitello, RN, Dr. Karl Deshrage, Al Dossantos, RPH, Dr. Steven Golinowski, Dr. Sabiha Haque, and Debbie Tirelli.

- October 24th, 2011 – A dinner program at TreDici in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity and effect on lipid levels. Attendees included: Jocquain Arcena, KAM Bartnett, Dr. Rita Chow, Dr.Gaisa, Dr. Livette Johnson, Dr. Barbara Johnston, Dr. Oscar Klein, Dr. Luz Amarilis Lugo, Sales Trainer McSherry, Mark Miller, RN, Janet Parker, Dr. John Steever, and Dr. Glenn Turett.

- November 2nd, 2011 – A dinner program at Alpha Fusion in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Bartnett, Dr. Adrian Demidont, Dr. Orin Douglas, Erin Mazza, PA, Ronica Mukerjee, NP, Steve Rodgers, NP, Dr. Urbina, and Susan Weiss, NP.

- November 2nd 2011 – A dinner program at Tamarind in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity and effect on lipid levels. Attendees included: Joaquin Arcena, KAM Bartnett, Monique Carasso, NP, Molly Cronin, PA, Reyna Cruz, Dr. Tessa Gomez, Dr. Haber, Vanessa Haney, Sales Trainer McSherry, Mark Miller, RN, Dr. Mullen, Dr. Salinas, and Senior Virology Sales Specialist Steve Smacchia.

- January 17, 2012 – A dinner program at Aldea Restaurant in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-

label concerning Prezista's effect on lipid levels. Attendees included: KAM Bartnett, Dr. Bungay, Dr. Ward Carpenter, Dr. Chavez, Dr. Stephen Dillon, Dr. Kaminsky, Dr. McMeeking, Dr. Mullen, Realtor Jessica Penelow, Susanne Rendeiro, NP, Dr. Nadim Salomon, and Senior Virology Sales Specialist Steve Smacchia.

- January 25th, 2012 – A dinner program at TreDici in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Bartnett, Jocquain Aracena, Reyna Cruz, Dr. Johnson, Dr. Klein, Sales Trainer McSherry, Mark Miller, RN, Janet Parker, Access and Reimbursement Director Eric Sherr, Maria Sires, Senior Virology Sales Specialist Steve Smacchia, Elizabeth Smith, PA, and Dr. Turett.

- February 23rd, 2012 – A dinner program at Morton's Steakhouse in Bethesda, MD featured a promotional speech by Dr. Segal-Maurer. Attendees included: Dr. Jose Chavez and Dr. Veronica Jenkins.

- February 29th, 2012 – A dinner program at Capital Grille in Tampa, FL featured a promotional speech by Dr. Segal-Maurer.

- March 1st, 2012 – A dinner program at Ristorante Claretta in Palm City, FL featured a promotional speech by Dr. Segal-Maurer.

- March 12th, 2012 – A dinner program at Le Vallauris in Palm Springs, CA featured a promotional speech by Dr. Segal-Maurer.

- April 5th, 2012 – A dinner program at Estia Restaurant in Philadelphia, PA featured a promotional speech by Dr. Segal-Maurer. Attendees included: Susan Daniluk, Rob Mascaro, Key Account Manager Robert Mumford, David Agosto, NP, David Downie, Sales Representative Ed Duca, Sheila Henry, Bertha Jackson, NP, Angela Kapalko, PA, Mable Lyons, and Christine Randazzo, RN.

- June 13th, 2012 – A dinner program at Rathbun's in Atlanta, GA featured a promotional speech by Dr. Segal-Maurer.

- March 11, 2014 – A dinner program in Syosset, NY featured a promotional speech by Dr. David Rubin.

197. Janssen's misleading messages regarding Intelence were delivered during the following dinner programs:

- April 22nd, 2010 – A dinner program at Novita in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Ms. Bartnett, Dr. Gaisa, Dr. Hitzeman, Lawrence Landphair, NP, Dr. Todd McNiff, Sales Trainer McSherry, Mark Miller, RN, Dr. Mullen, Dr. Salinas, Dr. William Shay, and Dr. Wehbeh.

- September 22nd, 2010 – A dinner program at Blue Water Grill in New York, NY featured a promotional speech by Dr. Kaminsky who promoted using Intelence once a day, and stated that it was the only NNRTI he was currently administering. Attendees included KAM Bartnett, Dr. Chavez, Dr. Bowers, Michelle Patton, Relator Jessica Penelow, and Susan Santoro.

- November 11th, 2010 – a dinner program at Philip Marie in New York, NY featured a promotional speech by Dr. Kaminsky who promoted the once a day use of Intelence, and discussed its off-label uses. Attendees included: KAM Ms. Bartnett, Dr. Leonidez De Guzman, Dr. Gweneth Francis, Dr. Robert Goldstein, Dr. Gomez, Dr. Sanjana Koshy, Sondra Middleton, PA, Dr. Akshay Manohar, Relator Jessica Penelow, Dr. Salomon, Dr. Usha Mathur-Wagh, and John Weber, RPA.

- November 11th, 2010 – A dinner program at Philip Marie in New York, NY featured a promotional speech by Dr. Kaminsky who promoted information off-label concerning the half-life of Intelence. Attendees included: KAM Ms. Bartnett, Dr. De Guzman, Dr. Francis, Dr. Goldstein, Dr. Gomez, Dr. Koshy, Sondra Middleton, PA, Dr. Monohar, Relator Jessica Penelow, Dr. Salomon, Dr. Mathur-Wagh, and John Weber, RPA.

- December 7th, 2010 – A dinner program at Spice Market in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Ms. Bartnett, Dr. Bungay, Dr. Carpenter, Dr. Dillon, Lawrence Landphair, NP, Dr. Mayer, Sales Trainer McSherry, Dr. Radix, and Susan Weiss, NP.

- December 8th, 2010 – A dinner program at Morton's Steakhouse in Great Neck, NY featured a promotional speech by Dr. Kaminsky who discussed information off-label including using Intelence once a day. Attendees included: KAM Bartnett, Relator Christine Brancaccio, Dr. Patricia Cole, Dr. Deshrage, Dr. Rachel Franck, Lulette Infante, RN, Jean Jacques, Regina Mengual, Martine Michel-Toure, David Natal, Joseph Navarra, RPH, Steven Orandello, Jack Pierro, Dr. Christine Sethna, Access and Reimbursement Director Eric Sherr, Marvin Siegel, Daniel Velazquez, and Suzanne Vento, RN.

- December 14th, 2010 – A dinner program at Spice Market in New York, NY featured a promotional speech by Dr. Kaminsky who promoted information off-label concerning using Intelence once a day. Attendees included: Dr. Leonard Berkowitz, Key Account Manager Reggie Cadet, Gregory Celestin, PA, Agnes Cha, and Senior Virology Sales Specialist Angelica Edwards.

- February 10th, 2011 – A dinner program at Morton's Steakhouse in Brooklyn, NY featured a promotional speech by Dr. Kaminsky. Senior Virology Sales Representative Jimmy Kwok also spoke and promoted off-label uses. Attendees included: Dr. Jamsheed Abadi, Dr. Lubin Augustin, Dr. Andre Brutus, Key Account Manager Reggie Cadet, District Manager Dolisi, Senior Virology Sales Specialist Angelica Edwards, Rebecca Fry, NP, Dr. Jesi Ramone, and Alla Shkolnik, NP.

- April 26th, 2011 – A dinner program at Pera in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Dr. Yusuf Afacan, Key Account Manager Reggie Cadet, Senior Virology Sales Representative Jimmy Kwok, Dr. Tevfik Mentes, Valerie Santangelo, NP, Alla Shkolnik, NP, and Dr. Mathur-Wagh.

- July 27th, 2011 – A dinner program at Spanish Tavern in Newark, NJ featured a promotional speech by Dr. Segal-Maurer who stated that Intelence could be used successfully once a day, and that she used it successfully this way in her own practice. Attendees included: Dr. Muhammad Afridi, Dr. Spartaco Bellomo, Sophie Ciszewski, RN, Rickey Danszey, Susan Garcia, Lillie Jones, Sandy Lenflin, Maria Lorenzo, Dr. Lewis Marton, Vieshia Morales, Veronica Naranso, Executive Virology Sales Representative Bryan O'Dea, Senior Virology Sales Representative Dennis O'Keeffe, Veronica Osero, Ms. Peterson, Dr. Lauro Rocha, Dominick Varsalone, RN, Keith Williams, and Kim Worrell.

- August 11th, 2011 – A dinner program at Novita in New York, NY featured a promotional speech by Dr. Segal-Maurer who discussed using Intelence once a day. Attendees included: KAM Bartnett, Lara Comotoa, Dr. Mayer, Sales Trainer Tim McSherry, Dr. Mullen, Dr. Radix, Dr. Jilan Shah, Dr. Belinda Velazquez, and Susan Weiss, NP.

- March 26th, 2012 – A dinner program at Tre Dici in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Joquain Arcena, KAM Ms. Bartnett, Reyna Cruz, Dr. Gaisa, Dr. Johnson, Dr. Klein, Dr. Lugo, Mark Miller, RN, Janet Parker, Relator Jessica Penelow, Senior Virology Sales Specialist Steve Smacchia, Eliyahith Smith, and Dr. Glenn Turrett.

b. <u>Speaker Programs</u>

198. Janssen also paid high-prescribing physicians to give speeches fraudulently marketing Prezista and Intelence to a crowd of physicians in other settings. These speaker programs provide opportunities for Janssen to hire individuals to speak on the off-label uses of their drugs. The speakers are generally paid $2,500 per talk, and are shuttled on all-expenses-paid trips across the country. They are often sent to other states not only to promote off-label, but also to accommodate their personal travel destinations: Dr. Sorana Segal-Maurer frequently asks to be sent to Chicago to watch baseball with her son or to California to shop with her daughter, Dr. Nadim Solomon prefers to be sent to Florida to visit family. Some other highly-compensated physician speakers included Dr. Don Kaminsky, Dr. Ridey Hsu and Dr. Andre Brutus.

199. Bartnett, Executive Key Account Manager at Janssen, organized these speaker programs. She would recruit doctors that she knew were willing to market Prezista and Intelence off-label. She would then prepare slide decks for these speakers with off-label marketing messages and send these doctors around the country to promote Prezista and Intelence off-label. KAM Bartnett would then prepare the speakers by telling them what to expect, who would be in attendance, and inform the speaker to share their anecdotal experience with the drug. These speakers earned significant fees from Janssen. If an individual was considered a high volume prescriber, they would be added to the list of speakers. Conversely, if they failed to reach a certain percentage, they were removed under the guise that they did not have enough patient experience. Dr. Juan Bailey from Beth Israel Medical Center was removed from the list because of his low market share and his unwillingness to promote the off-label studies. Other speakers removed from the list for low prescribing included: Dr. Stanley Yankovitz, Dr. Alex McMeeking, Dr. Jeffrey Green, Abby Freedberg NP, Karen Weisz NP, Rita Kelly NP, Linda Ording-Bauer NP and Kathy Aratoon NP. MedForce, an outside medical communications company, manages Janssen's speaker fund and maintains records of who attends the programs, who are the speakers, and how much money is paid.

200. As with dinner programs, Janssen would plant questioners in the audience during the question and answer session which would usually follow the one-hour presentation, to ask questions about the off-label use of the drug. This tactic disguised that Janssen organized the speaker events for the purpose of engaging in off-label marketing.

201. Moreover, Janssen paid speakers, including Drs. Segal-Maurer, Hsu, Kaminsky, Brutus, Salomon and Rashbaum to give speeches across the United States which included off-label

messages regarding Prezista. Ms. Bartnett provided these speakers with the same slide deck including the Binding Study slide, as the one used by the dinner program speakers.

202. For example, Janssen paid Dr. Ricky Hsu approximately $50,000 – $70,000 a year for speeches occurring all over the country (with a per speech payment of approximately $2,000-$2,500). Further, Dr. Segal-Maurer most likely received at least $50,000 per year for the last eight years of speeches on behalf of Janssen. In 2015, she gave 34 speeches paid for by Janssen. Moreover, Dr. Elizabeth Race gave 39 speeches on behalf of Janssen in 2015.

203. The prescribing habits of the paid speakers as well as the attendees were tracked and monitored by Janssen. For example, in 2012, Relator Penelow prepared an Excel spreadsheet for a district meeting with Manager Dolisi tracking the impact of the once-daily Intelence promotion. The spreadsheet was organized by paid speaker including, Drs. Kaminsky and Segal-Maurer, and showed the volume of the physicians' Intelence prescription writing as compared to the competitor drugs as well as their percentage growth in Intelence prescriptions.

204. Janssen's misleading messages regarding Prezista were delivered during the following speaker programs:

- February 23rd, 2010 – A speaker program at East Carolina University in Greenville, NC featured a promotional speech by Dr. Segal-Maurer who focused on differentiating Prezista from other PIs with regard to its binding affinity and effect on lipid levels.
- June 30th, 2010 – A speaker program at Provient Hospital in Chicago, IL featured a promotional speech by Dr. Segal-Maurer.
- November 30th, 2010 – A speaker program at Orion Health Group in Palm Springs, CA featured a promotional speech by Dr. Segal-Maurer who discussed Prezista's effect on lipid levels.
- December 9th, 2010 – A speaker program at Liberty Health Center in Jersey City, NJ featured a promotional speech by Dr. Segal-Maurer.
- December 10th, 2010 – A speaker program at Special Care Clinic in Flushing, NY featured a promotional speech by Dr. Segal-Maurer who discussed how lipid

friendly Prezista is for aging patients, and how it stays in the pocket longer and is more forgiving if a patient misses a dose. Attendees included: Relator Christine Brancaccio, Victor Cruz, Dr. Nyabilondi Ebama, Susan Kiernan, Dr. Kopacz, Noriel Mariano, Dr. David Rubin, Thema Tierney, and Dr. Wehbeh.

- March 16th, 2011 – A speaker program at SouthWest CARE Center in Santa Fe, NM featured a promotional speech by Dr. Segal-Maurer who discussed Prezista's favorable lipid profile. Attendees included: Dr. Betsy Brown, Dr. Warren Goldenberg, Dr. Trevor Hawkins, Cyatha Lujan, LPN, Peter Mengazo, Anthony Mueller, Luc Poppe, Senior Virology Sales Representative Brendan Snyder, Jeff Thomas, Larry Turner, and Wenoah Veikley, RN.

- February 14th, 2012 – A speaker program at Sunset Terrace Family Health Center in Brooklyn, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Reggie Cadet, Misty Chiu, NP, Dr. Deeptha Nedunchezian, Graciele Phlatts, LPN, and Jonathan Reynolds.

- February 23rd, 2012 – A speaker program at Montgomery County Health Department in Silver Springs, MD featured a promotional speech by Dr. Segal-Maurer. Attendees included Dr. Anthony Fernandez.

- February 29th, 2012 – A speaker program at Consultative Medicine at Daytona Beach, FL featured a promotional speech by Dr. Segal-Maurer.

- March 12th, 2012 – A speaker program at Desert AIDS Project in Palm Springs, CA and featured a promotional speech by Dr. Segal-Maurer.

- March 23rd, 2012 – A speaker program at Special Care Clinic in Flushing, NY featured a promotional speech by Dr. Segal-Maurer who discussed Prezista's effect on lipid levels. Attendees included: Lilia Albaneze, Relator Christine Brancaccio, Karen Lau, PA, Susan Kiernan, Dr. Nauman Piracha, Javeria Shakil, Dr. Peter Wasserman, and Dr. Sadia Zahid.

- April 5th, 2012 – A speaker program at Atlantic City Outpatient Clinic in Atlantic City, NJ featured a promotional speech by Dr. Segal-Maurer. Attendees included: Dr. Ricardo Barzaga, Terrence Crowley, Deb Downey, Jean Freeman, Anaris Gonzalez, Jean Haspel, NP, Dr. Dana Jones, Mike Khan, Christine McGloin, KAM Robert Mumford, Nana Noal, Cathy Stapleton, LPN, and Kay Wilsbach.

- April 12th, 2012 – A speaker program at Avia in Savannah, GA featured a promotional speech by Dr. Segal-Maurer.

205. Janssen's misleading messages regarding Intelence were delivered during the following speaker programs:

- March 18th, 2010 – A speaker program at Queens HIV Care Network in Jamaica, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Dr. Sandra Alvarez, KAM Bartnett, Stephen Cerny, Dr. Jennifer Chung, Brenda Collins, Janice Daste Sinkler, Francisco Diaz, NP, Andres Garcia, Dr. Deborah Greene, Michael Hadley, Delores Henley, Myung Hunt, Sonia Kaikai, Rosemary Lopez, Virginia Morales, Judy Pedraza, Gustavo Pedroza, Carin Pinney, Hector Resto, Melissa Robertson, RN, Nataly Rubio Torres, Janice Sickler, Robert Steptoe, and Michael Valentin.

- May 12th, 2010 – A speaker program at Village Center New York in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees were all social workers and included: KAM Bartnett, Daniel Calderon, PA, Steven Deitch, Karen Ford, Lois Gonzalez, Michael Hickey, RPH, Dr. Tiffany Le, Denise Mahon, RN, Ken Moberg, NP, Patricia Motus, OTR, Kelly Nicely, Bernice Noriega, Juan Olmedo, Maria Palanachud, Carmen Rodriguez, Danielle Sullivan, Joanne Tehrani, RD, Lisa Torres, and Dr. Janice Zimmerman.

- June 3rd, 2010 – A speaker program at West Midtown Medical Group in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: KAM Bartnett, Dr. Philip Gianelli, Kathryn Godly, PA, Daniel Painagua, PA, Dr. Steven Rappaport, Marianne Sciberras, Linda Soo, RN, and Blair Wiggins, PA.

- October 7th, 2010 – A speaker program at Town Total in New York, NY featured a promotional speech by Dr. Kaminsky who discussed using Intelence once a day. Attendees included: Heather Baek, KAM Ms. Bartnett, Lisa Boodram, Bernice Chen, PHAR, Fernando De Los Santos, PHAR, Michael Escuder, RPH, Aisha Heslop, Tasmiya Khan, PHAR, Hening Kwan, PHAR, Sam Merrill, Joseph Navaro, Michael Navaro, John Navarra, RPH, Joseph Navarra, RPH, Lynn Navarra, Mariya Rockman, Dr. Marvin Siegal, Usha Tejueaney, Dr. Cindy Wang, Lingyee Wong, Allison Yee, PHAR, and Irina Yusim, PHAR.

- October 15th, 2010 – A speaker program at NYHQ Special Care Clinic in Flushing, NY featured a promotional speech by Dr. Trevor Hawkins. Attendees included: KAM Ms. Bartnett, Relator Christine Brancaccio, Victor Cruz, Dr. Ebama, Lydia Gonzalez, Karen Hall, Susan Kiernan, Dr. Kopacz, Noriel Mariano, Dr. Rubin, Dr. Segal-Maurer, Dr. Tchikounzi, Theme Tierney, Dr. Wasserman, and Dr. Wehbeh.

- October 28th, 2010 – A speaker program at West Midtown Medical Center in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Katherine Godly, PA, Dr. Patricia Grosvenor, Yasmine Hubbard, Daniel Paniagua, PA, Dr. Rappaport, Marianne Riberras, Senior Virology Sales Specialist Steve Smacchia, and Blair Wiggins, P.A.

- October 29th, 2010 –A speaker program at Lutheran Medical Center in Brooklyn, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Gabriel Bananeo, Dr. Laura Beauchamps Bonnet, KAM Reggie Cadet, Dalila Dieppa, Dr.

David John, Katherine O'Neil, Alan Orfel, Dr. Marcelo Venegas-Pizarro, and Tielei Wong.

- November 11th, 2010 – A speaker program at Greenwich House in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: KAM Ms. Bartnett, Gloria Diaz, Judy Goris, Tracy Henry, PT, Veronica Martinez, R Membo Mcanell, Melissa Nordstrom, Judy Pedroza, Dr. Punyadech Photangtham, Louis Rayas, Susanne Rendeiro, NP, Angelica Rolon, and Alexandra Schaumber, MSW.

- December 7th, 2010 – A speaker program at Greewich House in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: Madeline Bellamy, Nicholas Calabrese, Gloria Davey, Judy Goris, Michael Hickey, RPH, George Jagatic, MS, Lee La Shore, Dr. Le, Denise Mahon, RN, Veronica Martinez, Ken Moberg, NP, Melissa Nordstrom, Susanne Rendeiro, NP, Carmen Rodriguez, Annette Scantebury, Senior Virology Sales Specialist Steve Smacchia, and Ilsa Torres.

- March 10th, 2011 – A speaker program at Lutheran Sunset Park Health Center in Brooklyn, NY featured a promotional speech from Dr. Kaminsky. Attendees included: Dr. Beauchamps Bonnet, Senior Virology Sales Specialist Angelica Edwards, Rebecca Fry, NP, Gloria Ivonne Moreno, Katherine O'Neil, Jason Siegel, ArronTorrel, and Dr. Marcelo Venegas Pizarro.

- July 27th, 2011 – A speaker program at Village Day Treatment in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: KAM Ms. Bartnett, Jay Dismukes, Veronica Gernett, MS, Michael Hickey, RPH, Kevin Hook, Denise Mahon, RN, Ken Moberg, NP, Kelly Nicely, CRNA, Bernice Noriega, Juan Olmeda, MSW, Amy Panichi, Carmen Rodriguez, Joanne Tehrani, RD, Lisa Torres, and Dr. Zimmerman.

- October 6th, 2011 – A speaker program at Newark Community Health Center in East Orange, NJ featured a promotional speech by Dr. Kaminsky who promoted using Intelence once a day. Attendees included: Latifah Abdus-solaen, Dr. Sebastian Kabiawu, Executive Virology Sales Representative Bryan O'Dea, O Ogunno, Ms. Peterson, and Sheila Roymono.

C. Janssen Fails to Meaningfully Investigate Complaints of Salespeople Pressured to Engage In Off-Label Marketing

206. In and around 2010, a New Jersey sales representative, Joanne Cesario, complained to upper management about Frank Murphy, her supervisor, pressuring her to use off-label marketing materials provided by Janssen to market Prezista and Intelence to doctors. As discussed above, Janssen had provided sales representatives with studies that would assist them in marketing

Prezista and Intelence off-label, but Janssen's official policy – which sales persons were expected to deviate from – prevented distribution of these materials.

207. In response, Janssen conducted a perfunctory investigation. Upon information and belief, each sales representative for the New Jersey office was called in to a meeting with attorneys and asked if they illegally marketed drugs off-label or were pressured to do so. The representatives met with one another and decided to protect Mr. Murphy by denying the allegations. In doing so, they ended the investigation.

208. Currently, neither Ms. Cesario nor Mr. Murphy is working for Janssen.

209. Janssen continues its practice of providing sales representatives with materials to assist in the off-label marketing of Prezista and Intelence.

VII. FALSE CLAIMS

A. Defendant Caused the Submission of False Claims for Misbranded and Off-Label Prezista and Intelence Prescriptions

210. Throughout the relevant time period, Defendant knowingly caused the submission of false claims for reimbursement of Prezista and Intelence. As alleged in detail above, during sales calls with physicians, dinner program and speaker programs nationwide, Defendant marketed Prezista and Intelence in a false and misleading way by misrepresenting a serious side effect associated with Prezista (that it increases lipids), overstating Prezista's efficacy (the Binding Study) and falsely claiming that Intelence is safe and effective taken once-a-day and by treatment-naïve patients. This conduct illegally misbranded the drug[3] and constituted off-label promotion.

211. As a result of Defendant's misleading messages regarding Prezista and Intelence, Defendant caused false claims to be submitted to the Government Health Care Programs for

[3] Again, a drug is "misbranded" if its labeling (defined very broadly) and advertising is false and misleading in any way.

reimbursement. Each of the claims for Prezista and Intelence included an express and/or implied certification of compliance with federal and state law and regulations. Those certifications were false because the drugs were misbranded in violation of the FDCA and/or off-label. Further, those certifications were false or fraudulent because they falsely represented that Prezista and Intelence were "reasonable and necessary" for the treatment of the patients and, therefore, the associated claims are ineligible for reimbursement.

212. While the cost of providing Prezista and Intelence for on-label and non-misbranded uses to Government Health Care Program recipients is covered by the Government Health Care Programs, including Medicare and Medicaid, the cost of off-label and misbranded prescriptions is not. Since Prezista and Intelence were promoted off-label, were not "reasonable and necessary" for the treatment of some patients and misbranded, claims for prescriptions caused by this misconduct are not reimburseable.

213. Knowingly submitting or causing the submission of claims for prescription drugs which are not reimburseable creates liability under the FCA. Thus, these claims to the government for reimbursement caused to be submitted by Defendant's unlawful conduct constitute violations of section 3729 of the FCA and relevant State FCAs.

B. Defendant Caused the Submission of False Claims in Violation of the Anti-Kickback Statute

214. Defendant's payments to physicians for dinner and speaker programs which included misleading and off-label messages regarding Prezista and Intelence as well as other remuneration provided the means for Defendant to pay kickbacks to physicians to induce prescriptions of Prezista and Intelence. Any prescriptions for Prezista and Intelence written by said physicians during the relevant time period were tainted by these kickbacks.

215. Additionally, Defendant caused claims to be submitted to the Government Health Care Programs for reimbursement. Each of the claims for Prezista and Intelence included an express and/or implied certification of compliance with federal and state law and regulations. Those certifications were false because they were in violation of the AKS. Further, since 2010, the AKS now expressly states that a violation of the AKS constitutes a "false or fraudulent" claim under the False Claims Act. (42 U.S.C. § 1320(a)-7b(g)).

216. Further, compliance with the AKS is a material condition of payment under Medicare and Medicaid.[4] Falsely certifying compliance with a condition of payment, or causing another to falsely certify compliance with a condition of payment, incurs liability under the FCA.[5]

217. Thus, the claims to the Government Health Care Programs that the Defendant's unlawful conduct caused constitute violations of Section 3729 of the FCA and relevant State FCAs.

VIII. COUNTS

COUNT I

FEDERAL FALSE CLAIMS ACT, 31 U.S.C.A. §§ 3729(a)(1)(A), (B) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

218. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

[4] *See United States et al. ex rel. Westmoreland v. Amgen Inc.*, 2011 U.S. App. LEXIS 15036 (1st Cir. July 22, 2011); *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 2011 U.S. App. LEXIS 10972 (1st Cir. June 1, 2011); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *United States ex rel. Conner v. Salina Regional Health Ctr.*, 543 F.3d 1211, 1223 n.8 (10th Cir. 2008); *United States ex rel. McNutt v. Haleyville Medical Supplies*, 423 F.3d 1256, 1259-1260 (11th Cir. 2005); *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

[5] *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 2011 U.S. App. LEXIS 10972, *36 (1st Cir. June 1, 2011) ("unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party); s*ee also United States v. Rivera*, 55 F.3d 703, 710-712 (1st Cir. 1995) (stating that a "false claim may be presented through an innocent third party" (citations omitted).

219. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by the Government Health Care Programs. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to the United States in violation of Section 3729(a)(1)(A) of the Act.

220. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to the United States, in violation of Section 3729(a)(1)(B) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

221. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT II

FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(A) FOR UNLAWFUL KICKBACKS

222. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

223. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value, such as free trips, for the purpose of, among

other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to the Government Health Care Programs constituted a false or fraudulent claim for payment.

224. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to the United States in violation of Section 3729(a)(1)(A) of the Act.

225. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT III

CALIFORNIA FALSE CLAIMS ACT
CAL. GOV'T CODE §§ 12651(A)(1), (2)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

226. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

227. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by California. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to California in violation of Section 12651(a)(1) of the Act.

228. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to California, in violation of Section 12651(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false

statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

229. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to California in violation of 12651(a)(1) and (2) of the Act.

230. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT IV

CALIFORNIA FALSE CLAIMS ACT
Cal. Gov't Code § 12651(a)(1)
FOR UNLAWFUL KICKBACKS

231. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

232. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to California constituted a false or fraudulent claim for payment.

233. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to California in violation of Section 12651(a)(1) of the Act.

234. As a result of Defendant's knowing violations of the Act, California has sustained actual damages.

COUNT V

COLORADO MEDICAID FALSE CLAIMS ACT C.R.S.A. §§ 25.5-4-305(1)(A), (B) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

235. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

236. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Colorado. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Colorado in violation of Section 25.5-4-305(1)(a) of the Act.

237. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Colorado, in violation of Section 25.5-4-305(1)(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

238. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Colorado in violation of Section 25.5-4-305(1)(a) and (1)(b) of the Act.

239. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT VI

COLORADO MEDICAID FALSE CLAIMS ACT C.R.S. § 25.5-4-305(1)(a) FOR UNLAWFUL KICKBACKS

240. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

241. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Colorado constituted a false or fraudulent claim for payment.

242. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Colorado in violation of Section 25.5-4-305(1)(a) of the Act.

243. As a result of Defendant's knowing violations of the Act, Colorado has sustained actual damages.

COUNT VII

CONNECTICUT FALSE CLAIMS ACT CONN. GEN. STAT. ANN. §§ 4-275(a)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

244. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

245. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients

and/or claims submitted due to off-label promotion are not eligible for reimbursement by Connecticut. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 4-275(a)(1) of the Act.

246. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Connecticut, in violation of Section 4-275(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

247. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 17b-301b(a)(1) and (a)(2) of the Act.

248. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT VIII

CONNECTICUT FALSE CLAIMS ACT CONN. GEN. STAT. ANN.§ 4-275(a)(1) FOR UNLAWFUL KICKBACKS

249. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

250. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks

which was subsequently presented to Connecticut constituted a false or fraudulent claim for payment.

251. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 4-275(a)(1) of the Act.

252. As a result of Defendant's knowing violations of the Act, Connecticut has sustained actual damages.

COUNT XL

DELAWARE FALSE CLAIMS AND REPORTING ACT DEL CODE ANN. TIT. 6, §§ 1201(A)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

253. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

254. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Delaware. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Delaware in violation of Section 1201(a)(1) of the Act.

255. Further, throughout the relevant time period, Defendant through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Delaware, in violation of Section 1201(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is

"lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

256. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Delaware in violation of Section 1201(a)(1) and (a)(2) of the Act.

257. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT X

DELAWARE FALSE CLAIMS AND REPORTING ACT
Del Code Ann. Tit. 6, §§1201(a)(1)
FOR UNLAWFUL KICKBACKS

258. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

259. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Delaware constituted a false or fraudulent claim for payment.

260. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Delaware in violation of Section 1201(a)(1) of the Act.

261. As a result of Defendant's knowing violations of the Act, Delaware has sustained actual damages.

COUNT XI

FLORIDA FALSE CLAIMS ACT
FLA. STAT. ANN. §§ 68.082(2)(A), (B)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

262. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

263. Throughout the relevant time period, Defendant caused submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Florida. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Florida in violation of Section 68.082(2)(a) of the Act.

264. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Florida, in violation of Section 68.082(2)(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

265. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Florida in violation of Section 68.082(2)(a) and (2)(b) of the Act.

266. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XII

FLORIDA FALSE CLAIMS ACT
Fla. Stat. Ann. §§68.082(2)(a)
FOR UNLAWFUL KICKBACKS

267. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

268. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Florida constituted a false or fraudulent claim for payment.

269. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Florida in violation of Section 68.082(2)(a) of the Act.

270. As a result of Defendant's knowing violations of the Act, Florida has sustained actual damages.

COUNT XIII

GEORGIA FALSE MEDICAID CLAIMS ACT
GA. CODE ANN. §§ 49-4-168.1(A)(1), (2)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

271. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

272. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients

and/or claims submitted due to off-label promotion are not eligible for reimbursement by Georgia. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Georgia in violation of Section 49-4-168.1(a)(1) of the Act.

273. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Georgia, in violation of Section 49-4-168.1(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

274. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Florida in violation of Section 49-4-168.1(a)(1) and (a)(2) of the Act.

275. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XIV

GEORGIA FALSE MEDICAID CLAIMS ACT
Ga. Code Ann. §§ 49-4-168.1(a)(1)
FOR UNLAWFUL KICKBACKS

276. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

277. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in

part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Georgia constituted a false or fraudulent claim for payment.

278. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Georgia in violation of Section 49-4-168(a)(1) of the Act.

279. As a result of Defendant's knowing violations of the Act, Georgia has sustained actual damages.

COUNT XV

HAWAII FALSE CLAIMS ACT
HAW. REV. STAT. §§ 661-21(A)(1), (2)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

280. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

281. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Hawaii. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Hawaii in violation of Section 661-21(a)(1) of the Act.

282. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Hawaii, in violation of Section 661-21(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is

"lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

283. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Hawaii in violation of Section 661-21(a)(1) of the Act.

284. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XVI

HAWAII FALSE CLAIMS ACT
Haw. Rev. Stat. §661-21(a)(1)
FOR UNLAWFUL KICKBACKS

285. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

286. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Hawaii constituted a false or fraudulent claim for payment.

287. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Hawaii in violation of Section 661-21(a)(1) of the Act.

288. As a result of Defendant's knowing violations of the Act, Hawaii has sustained actual damages.

COUNT XVII

ILLINOIS FALSE CLAIMS ACT
740 IL.C.S. §§ 175/3(A)(1)(A), (B)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

289. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

290. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Illinois. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Illinois in violation of Section 175/3(a)(1)(A) of the Act.

291. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Illinois, in violation of Section 175/3(a)(1)(B) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

292. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to payment to Illinois in violation of Section 175/3(a)(1)(A) and (B) of the Act.

293. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XVIII

ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. §§175/3(a)(1)(A) FOR UNLAWFUL KICKBACKS

294. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

295. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Illinois constituted a false or fraudulent claim for payment.

296. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Illinois in violation of Section 175/3(a)(1)(A) of the Act.

297. As a result of Defendant's knowing violations of the Act, Illinois has sustained actual damages.

COUNTY XIX

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IND. CODE ANN. §§ 5-11-5.5-2(B)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

298. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

299. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients

and/or claims submitted due to off-label promotion are not eligible for reimbursement by Indiana. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Indiana in violation of Section 5-11-5.5-2(b)(1) of the Act.

300. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Indiana, in violation of Section 5-11-5.5-2(b)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

301. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Indiana in violation of Section 5-11-5.5-2(b)(1) and (2) of the Act.

302. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XX

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
Ind. Code Ann. §§5-11-5.5-2(b)(1)
FOR UNLAWFUL KICKBACKS

303. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

304. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in

part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Indiana constituted a false or fraudulent claim for payment.

305. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Indiana in violation of Section 5-11-5.5-2(b)(1) of the Act.

306. As a result of Defendant's knowing violations of the Act, Indiana has sustained actual damages.

COUNTY XXI

IOWA FALSE CLAIMS ACT
IOWA CODE ANN. § 685.2(1)(A), (B)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

307. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

308. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Iowa. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Iowa in violation of Section 685.2(1)(a) of the Act.

309. Further, throughout the relevant time period, Defendant, through its off-label marketing, for drugs that are not "reasonable and necessary" for the treatment of patients and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Iowa, in violation of Section 685.2(1)(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-

neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

310. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Iowa in violation of Section 685.2(1)(a) of the Act.

311. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXII

IOWA FALSE CLAIMS ACT
IOWA Code ANN. § 685.2(1)(a)
FOR UNLAWFUL KICKBACKS

312. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

313. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Iowa constituted a false or fraudulent claim for payment.

314. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Iowa in violation of Section 685.2(1)(A) of the Act.

315. As a result of Defendants' knowing violations of the Act, Iowa has sustained actual damages.

COUNT XIII

LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW LA. REV. STAT. ANN. §§ 46:438.3(A), (B) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

316. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

317. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Louisiana. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Louisiana in violation of Section 46:438.3(A) of the Act.

318. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Louisiana, in violation of Section 46:438.3(B) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

319. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Louisiana in violation of Section 46:438.3(A) of the Act.

320. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXIV

LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW LA. REV. STAT. §46:438.3(A) FOR UNLAWFUL KICKBACKS

321. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

322. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Louisiana constituted a false or fraudulent claim for payment.

323. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Louisiana in violation of Section 46:438.3(A) of the Act.

324. As a result of Defendant's knowing violations of the Act, Louisiana has sustained actual damages.

COUNT XXV

MASSACHUSETTS FALSE CLAIMS LAW MASS. GEN. LAWS ANN. CH. 12 §§ 5B(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

325. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

326. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients

and/or claims submitted due to off-label promotion are not eligible for reimbursement by Massachusetts. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Massachusetts in violation of Section 5B(1) of the Act.

327. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Massachusetts, in violation of Section 5B(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

328. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Massachusetts in violation of Section 5B(1) and (2) of the Act.

329. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXVI

MASSACHUSETTS FALSE CLAIMS LAW MASS. GEN. LAWS CH. 12 §§5B(1) FOR UNLAWFUL KICKBACKS

330. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

331. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks

which was subsequently presented to Massachusetts constituted a false or fraudulent claim for payment.

332. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Massachusetts in violation of Section 5B(1) of the Act.

333. As a result of Defendant's knowing violations of the Act, Massachusetts has sustained actual damages.

COUNT XXVII

MICHIGAN MEDICAID FALSE CLAIMS ACT
MICH. COMP. LAWS. §§ 400.607(2), (3)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS
OF PREZISTA AND INTELENCE

334. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

335. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Michigan. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Michigan in violation of Section 400.607(2) of the Act.

336. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Michigan, in violation of Section 400.607(3) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is

"lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

337. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Michigan in violation of Section 400.607(2) of the Act.

338. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXVIII

MICHIGAN MEDICAID FALSE CLAIMS ACT MICH. COMP. LAWS. §§400.607(1) FOR UNLAWFUL KICKBACKS

339. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

340. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Michigan constituted a false or fraudulent claim for payment.

341. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Michigan in violation of Section 400.607(1) of the Act.

342. As a result of Defendant's knowing violations of the Act, Michigan has sustained actual damages.

COUNT XXIX

THE MINNESOTA FALSE CLAIMS ACT
MINN. STAT. ANN. §§ 15C.02(A)(1), (2)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS
OF PREZISTA AND INTELENCE

343. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

344. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Minnesota. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Minnesota in violation of Section 15C.02(a)(1) of the Act.

345. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Minnesota, in violation of Section 15C.02(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

346. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Minnesota in violation of Section 15C.02(a)(1) and (a)(2) of the Act.

347. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXX

THE MINNESOTA FALSE CLAIMS ACT
MINN. STAT. §§15C.02(A)(1)
FOR UNLAWFUL KICKBACKS

348. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

349. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Minnesota constituted a false or fraudulent claim for payment.

350. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Minnesota in violation of Section 15C.02(a)(1) of the Act.

351. As a result of Defendant's knowing violations of the Act, Minnesota has sustained actual damages.

COUNT XXXI

MONTANA FALSE CLAIMS ACT
MONT. CODE ANN. §§ 17-8-403(1)(A), (B)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS
OF PREZISTA AND INTELENCE

352. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

353. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for

misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Montana. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Montana in violation of Section 17-8-403(1)(a) of the Act.

354. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Montana, in violation of Section 17-8-403(1)(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

355. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Montana in violation of Section 17-8-403(1)(a) of the Act.

356. As a result of Defendant' knowing violations of the Act, the United States has sustained actual damages.

COUNT XXXII

MONTANA FALSE CLAIMS ACT
MONT. CODE ANN. § 17-8-403(1)(A)
FOR UNLAWFUL KICKBACKS

357. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

358. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in

part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Montana constituted a false or fraudulent claim for payment.

359. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Montana in violation of Section 17-8-403(1)(a) of the Act.

360. As a result of Defendants' knowing violations of the Act, Montana has sustained actual damages.

COUNT XXXIII

THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT
Nev. Rev. Stat. Ann. §§ 357.040(1)(a), (b)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

361. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

362. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Nevada. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Nevada in violation of Section 357.040(1)(a) of the Act.

363. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Nevada, in violation of Section 357.040(1)(b) of the Act. Defendant has

364. knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-

neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

365. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Nevada in violation of Section 357.040(1)(a) of the Act.

366. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXXIV

THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT NEV. REV. STAT. ANN. §§357.040(1)(a) FOR UNLAWFUL KICKBACKS

367. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

368. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Nevada constituted a false or fraudulent claim for payment.

369. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Nevada in violation of Section 357.040(1)(a) of the Act.

370. As a result of Defendant's knowing violations of the Act, Nevada has sustained actual damages.

COUNT XXXV

NEW JERSEY FALSE CLAIMS ACT
N.J. STAT. ANN. §§ 2A:32C-3(A), (B)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS
OF PREZISTA AND INTELENCE

371. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

372. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by New Jersey. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New Jersey in violation of Section 2A:32C-3(a) of the Act.

373. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to New Jersey, in violation of Section 2A:32C-3(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

374. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New Jersey in violation of Section 2A:32C-3(a) of the Act.

375. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXXVI

NEW JERSEY FALSE CLAIMS ACT
N.J. STAT. § 2A:32C-3(a)
FOR UNLAWFUL KICKBACKS

376. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

377. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to New Jersey constituted a false or fraudulent claim for payment.

378. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New Jersey in violation of Section 2A:32C-3(a) of the Act.

379. As a result of Defendant's knowing violations of the Act, New Jersey has sustained actual damages.

COUNT XXXVII

NEW MEXICO FRAUD AGAINST TAXPAYERS ACT
N.M. STAT. ANN. §§ 27-14-4 (A), (C)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS
OF PREZISTA AND INTELENCE

380. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

381. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for

misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by New Mexico. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New Mexico in violation of Section 27-14-4(A) of the Act.

382. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to New Mexico, in violation of Section 27-14-4(C) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

383. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New Mexico in violation of Section 27-14-4(A) and (C) of the Act.

384. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XXXVIII

NEW MEXICO FRAUD AGAINST TAXPAYERS ACT N.M. STAT. ANN. §§27-14-4 (A) FOR UNLAWFUL KICKBACKS

385. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

386. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in

part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to New Mexico constituted a false or fraudulent claim for payment.

387. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New Mexico in violation of Section 27-14-4(A) of the Act.

388. As a result of Defendant's knowing violations of the Act, New Mexico has sustained actual damages.

COUNT XXXIX

NEW YORK FALSE CLAIMS ACT
N.Y. STATE FIN. LAW §§ 189(1)(A), (B)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

389. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

390. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by New York. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New York in violation of Section 189(1)(a) of the Act.

391. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to New York, in violation of Section 189(1)(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is

"lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

392. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New York in violation of Section 189(1)(a) and (1)(b) of the Act.

393. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XL

NEW YORK FALSE CLAIMS ACT
N.Y. STATE FIN. §§189(1)(a)
FOR UNLAWFUL KICKBACKS

394. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

395. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to New York constituted a false or fraudulent claim for payment.

396. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to New York in violation of Section 189(1)(a) of the Act.

397. As a result of Defendant's knowing violations of the Act, New York has sustained actual damages.

COUNT XLI

NORTH CAROLINA FALSE CLAIMS ACT
N.C. GEN. STAT. ANN. §§ 1-607(A)(1), (2)
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS
OF PREZISTA AND INTELENCE

398. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

399. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by North Carolina. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to North Carolina in violation of Section 1-607(a)(1) of the Act.

400. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to North Carolina, in violation of Section 1-607(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

401. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to North Carolina in violation of Section 1-607(a)(1) of the Act.

402. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XLII

NORTH CAROLINA FALSE CLAIMS ACT 2009-554 C. SESS. LAWS § 1-607(a)(1) FOR UNLAWFUL KICKBACKS

403. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

404. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to North Carolina constituted a false or fraudulent claim for payment.

405. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to North Carolina in violation of Section 1-607(a)(1) of the Act.

406. As a result of Defendant's knowing violations of the Act, North Carolina has sustained actual damages.

COUNT XLIII

OKLAHOMA MEDICAID FALSE CLAIMS ACT OKLA. STAT. ANN. TIT. 63 §§ 5053.1(B)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

407. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

408. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for

misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Oklahoma. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Oklahoma in violation of Section 5053.1(B)(1) of the Act.

409. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Oklahoma, in violation of Section 5053.1(B)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

410. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to klahoma in violation of Section 5053.1(B)(1) and (B)(2) of the Act.

411. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XLIV

OKLAHOMA MEDICAID FALSE CLAIMS ACT OKLA. STAT. TIT. 63 §§5053.1(B)(1) FOR UNLAWFUL KICKBACKS

412. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

413. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things,

inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Oklahoma constituted a false or fraudulent claim for payment.

414. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Oklahoma in violation of Section 5053.1(B)(1) of the Act.

415. As a result of Defendant's knowing violations of the Act, Oklahoma has sustained actual damages.

COUNT XLV

RHODE ISLAND FALSE CLAIMS ACT R.I. GEN. LAWS ANN. §§ 9-1.1-3(A)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

416. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

417. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Rhode Island. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Rhode Island in violation of Section 9-1.1-3(a)(1) of the Act.

418. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Rhode Island, in violation of Section 9-1.1-3(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false

statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

419. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Rhode Island in violation of Section 9-1.1-3(a)(1) and (a)(2) of the Act.

420. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XLVI

RHODE ISLAND FALSE CLAIMS ACT
R.I. GEN. LAWS § 9-1.1-3(a)(1)
FOR UNLAWFUL KICKBACKS

421. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

422. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Rhode Island constituted a false or fraudulent claim for payment.

423. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Rhode Island in violation of Section 9-1.1-3(a)(1) of the Act.

424. As a result of Defendant's knowing violations of the Act, Rhode Island has sustained actual damages.

COUNT XLVII

TENNESSEE MEDICAID FALSE CLAIMS ACT TENN. CODE ANN. §§ 71-5-182(A)(1)(A), (B) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

425. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

426. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Tennessee. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Tennessee in violation of Section 71-5-182(a)(1)(A) of the Act.

427. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Tennessee, in violation of Section 71-5-182(a)(1)(B) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

428. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Tennessee in violation of Section 71-5-182(a)(1)(A) and (B) of the Act.

429. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT XLVIII

TENNESSEE MEDICAID FALSE CLAIMS ACT TENN. CODE ANN. §§71-5-182(1)(A) FOR UNLAWFUL KICKBACKS

430. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

431. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Tennessee constituted a false or fraudulent claim for payment.

432. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Tennessee in violation of Section 71-5-182(1)(A) of the Act.

433. As a result of Defendant's knowing violations of the Act, Tennessee has sustained actual damages.

COUNT XLIX

TEXAS MEDICAID FRAUD PREVENTION LAW TEX. HUM. RES. CODE ANN. §§ 36.002(1), (4) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

434. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

435. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for

misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Texas. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Texas in violation of Section 36.002(1) of the Act.

436. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Texas, in violation of Section 36.002(4) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

437. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Texas in violation of Section 36.002(1) of the Act.

438. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT L

TEXAS MEDICAID FRAUD PREVENTION LAW TEX. HUM. RES. CODE ANN. §§36.002(1) FOR UNLAWFUL KICKBACKS

439. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

440. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things,

inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Texas constituted a false or fraudulent claim for payment.

441. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Texas in violation of Section 36.002(1) of the Act.

442. As a result of Defendant's knowing violations of the Act, Texas has sustained actual damages.

COUNT LI

VIRGINIA FRAUD AGAINST TAXPAYERS ACT VA. CODE ANN. §§ 8.01-216.3(A)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

443. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

444. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Virginia. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Virginia in violation of Section 8.01-216.3(A)(1) of the Act.

445. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Virginia, in violation of Section 8.01-216.3(A)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim

that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

446. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Virginia in violation of Section 8.01-216.3(A)(1) and (A)(2) of the Act.

447. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT LII

VIRGINIA FRAUD AGAINST TAXPAYERS ACT
VA. CODE ANN. §§8.01-216.3(A)(1)
FOR UNLAWFUL KICKBACKS

448. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

449. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Virginia constituted a false or fraudulent claim for payment.

450. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Virginia in violation of Section 8.01-216.3(A)(1) of the Act.

451. As a result of Defendant's knowing violations of the Act, Virginia has sustained actual damages.

COUNT LIII

WASHINGTON MEDICAID FRAUD FALSE CLAIM ACT REV. CODE WASH. ANN. §§ 74.66.020(1)(a), (b) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

452. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

453. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by Washington. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Washington in violation of Sections 74.66.020(1)(a) of the Act.

454. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Washington in violation of Section 74.66.020(1)(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

455. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Washington in violation of Sections 48.80.030(1) and 48.80.030(2) of the Act.

456. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT LIV

WASHINGTON MEDICAID FRAUD FALSE CLAIM ACT REV. CODE WASH. ANN. §§ 74.66.020(1)(a) FOR UNLAWFUL KICKBACKS

457. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

458. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Washington constituted a false or fraudulent claim for payment.

459. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Washington in violation of Section 74.66.020(1)(a) of the Act.

460. As a result of Defendant's knowing violations of the Act, Washington has sustained actual damages.

COUNT LV

DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. CODE §§ 2-381.02(A)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE

461. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

462. Throughout the relevant time period, Defendant caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for

misbranded drugs, for drugs that are not "reasonable and necessary" for the treatment of patients and/or claims submitted due to off-label promotion are not eligible for reimbursement by District of Columbia. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to District of Columbia in violation of Section 2-381.02(a)(1) of the Act.

463. Further, throughout the relevant time period, Defendant, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to the District of Columbia, in violation of Section 2-381.02(a)(2) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other PI drugs, and Intelence is safe and effective for once a day use and for treatment-naïve patients.

464. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to District of Columbia in violation of Section 2-381.02(a)(1) and (a)(2) of the Act.

465. As a result of Defendant's knowing violations of the Act, the United States has sustained actual damages.

COUNT LVI

DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. CODE ANN. §§2-308.14(a)(1) FOR UNLAWFUL KICKBACKS

466. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

467. Throughout the relevant time period, Defendant has knowingly and willfully made unlawful payments to physicians and other health care professionals in connection with dinner and

speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Health Care Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to District of Columbia constituted a false or fraudulent claim for payment.

468. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to District of Columbia in violation of Section 2-308.14(a)(1) of the Act.

469. As a result of Defendant's knowing violations of the Act, District of Columbia has sustained actual damages.

REQUESTS FOR RELIEF

WHEREFORE, Relators, on behalf of the United States and the Plaintiff States, demands that judgment be entered in their favor and against Defendant for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred Dollars ($5,500.00) for each false claim, and any other recoveries or relief provided for under the Federal False Claims Act.

This Request also includes, with respect to the state statutes cited above, the maximum damages permitted by those statutes and the maximum fine or penalty permitted by those statutes, and any other recoveries or relief provided for under the State FCA's.

Further, Relators request that they receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States and the Plaintiff States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs.

Relators request that their award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Dated: June 30, 2017

Respectfully submitted,

/s Peter S. Pearlman

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Attorneys for Plaintiff Relators

Kal7703347

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Second Amended Complaint Pursuant to the Federal False Claims Act, 31 U.S.C. §§3729 *Et Seq.* and Pendent State False Claims Act was served on this 30th day of June, 2017, via the Court's electronic filing system (ECF) upon all counsel of record.

/s Peter S. Pearlman