UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
EASTERN DIVISION

UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA, and THE DISTRICT OF COLUMBIA,

ex rel. RONALD E. KAVANAGH,

PLAINTIFFS AND RELATOR,

v.

MERCK & CO., INC., a New Jersey Corporation; SCHERING-PLOUGH, wholly owned and merged with Merck, and ORGANON, N.V., a subsidiary of Merck purchased by Schering-Plough from AZKO NOBEL, N.V., a foreign company; PFIZER, INC. a Delaware Corporation; JOHNSON AND JOHNSON, a New Jersey corporation; and ELI LILLY & CO., an Indiana Corporation,

DEFENDANTS.

CIVIL ACTION NO.

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

FALSE CLAIMS ACT COMPLAINT

JURY TRIAL DEMANDED

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RONALD E. KAVANAGH, by his attorneys, Baum, Hedlund, Aristei & Goldman, P.C. and Bailey & Glasser LLP brings this action on behalf of the United States of America for treble damages and civil penalties arising from Defendants' MERCK & CO., INC. and its wholly owned merged entity, SCHERING-PLOUGH, which acquired ORGANON, from AZKO NOBEL, a chemical company (collectively referred to as "Merck"), PFIZER, INC. (hereinafter referred to as "Pfizer"), JOHNSON AND JOHNSON (hereinafter referred to as "J&J"), and ELI LILLY & COMPANY (hereinafter referred to as "Lilly"), conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). The violations arise out of false claims for payment made to Medicare, Medicaid, Tricare and other federally funded government healthcare programs (hereinafter, collectively the "Government Healthcare Programs") for the drugs Saphris® (asenapine), Geodon®, Risperdal®, and Zyprexa® in all their formulations.

This action is also brought under the respective *qui tam* provisions of False Claims Acts (or similarly named) on behalf of the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, the District of Columbia, Virginia, and Wisconsin. These states, together with the United States, are hereafter collectively referred to as "the Government."

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the Government arising from false and fraudulent records, statements, and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et. seq., as amended ("the FCA" or "the Act").

2. As set forth below, Defendants' acts also constitute violations of the California False Claims Act, Cal. Govt Code §12650 *et seq*.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 *et seq*.; the Florida False Claims Act, Fla. Stat. §68.081 *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code Ann. §49-4-168 *et seq*.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq*.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §17511-8; the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §5-11-5.5-1 *et seq*.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §437.1 *et seq*.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq*.; the Michigan Medicaid False Claims Act, Mich. Comp. Laws §400.601 *et seq*.; the Minnesota False Claims Act, Minn.Stat. §§ 15C.01 *et seq*.; the Montana False Claims Act, Mont. Code Ann. §17-8-401 *et seq*.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 *et seq*.; the New Jersey False Claims Act, N.J. Stat. §2A:32C-l *et seq*.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-l *et seq*.; the New York False Claims Act, N.Y. State Fin. §187 *et seq*.; the North Carolina False Claims Act, N.C.G.S., §1-605 *et seq*.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053 *et seq*.; the Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1 *et seq*.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq*.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 *et seq*.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 *et seq*.; the Wisconsin False Claims Act for Medical Assistance, Wis. Stat. §20.931 *et seq*.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 *et seq*.

3. As alleged herein, Merck has caused thousands of false claims to be made on federal and state health care programs related to Saphris® (asenapine).

4. As alleged herein, Pfizer has caused thousands of false claims to be made on federal and state health care programs related to Geodon®.

5. As alleged herein, J&J has caused thousands of false claims to be made on federal and state health care programs related to Risperdal®.

6. As alleged herein, Lilly has caused thousands of false claims to be made on federal and state health care programs related to Zyprexa®.

7. Risperdal® was approved for marketing in the United States in 1993.

8. Zyprexa® was approved for marketing in the United States in 1996.

9. Geodon® was approved for marketing in the United States in February 2001.

10. Saphris® was approved for marketing in the United States in August 2009.

11. Risperdal®, Geodon®, Zyprexa® and Saphris® are antipsychotic medications that have been improperly marketed to patients with mild to moderate mania diagnosed with bipolar I disorder. These drugs lack efficacy in these less severely ill patients.

12. Merck masked the efficacy issue regarding Saphris® by including in study populations a substantial number of severely manic patients, for whom this antipsychotic does show improvement, and mixing these more seriously ill patients in with less severely ill patients, creating a false impression of efficacy across a larger patient population than the drug has actually demonstrated.

13. This same and similar improper methodology was employed by J&J, Pfizer and Lilly in obtaining approval for their respective drugs, Risperdal®, Geodon® and Zyprexa®.

14. Consequently, these atypical antipsychotics are being fraudulently marketed to millions of mild/moderately ill mania patients, for whom no efficacy has been demonstrated, potentially exposing them to the drugs' harmful side effects with no proven benefit.

15. Marketing by Merck and prescribing Saphris® to mild/moderately manic patients is, in effect, off label.

16. Marketing by J&J and prescribing Risperdal® to mild/moderately manic patients is, in effect, off label.

17. Marketing by Pfizer and prescribing Geodon® to mild/moderately manic patients is, in effect, off label.

18. Marketing by Lilly and prescribing Zyprexa® to mild/moderately manic patients is, in effect, off label.

19. There are no clinical trial results showing efficacy for Saphris®, Risperdal®, Geodon® and Zyprexa® amongst this patient population. Consequently, they are unsafe when used as recommended in the labeling, which is false and misleading, and approval and introduction of the drugs into interstate commerce is in violation of the Food, Drug and Cosmetic Act (FDCA).

20. By masking the lack of efficacy, Merck, J&J, Pfizer and Lilly, atypical antipsychotic manufacturers, are causing false claims to be paid by federal and state health care programs.

21. Saphris®' defects, of which there are several, are shared by Risperdal®, Geodon® and Zyprexa®.

22. Merck, Pfizer, J&J and Lilly masked the efficacy issue by including in study populations a substantial number of severely manic patients, for whom these antipsychotics do show improvement, and mixing these more seriously ill patients in with less severely ill patients, creating a false impression of efficacy across a larger patient population than the drugs have actually demonstrated.

23. This disproportionate sampling skewed the results for Saphris®, Risperdal® Geodon® and Zyprexa®.

24. Consequently, Saphris®, Risperdal®, Geodon® and Zyprexa® are being fraudulently marketed to millions of mild/moderately ill mania patients, for whom no efficacy has been demonstrated, potentially exposing them to the drugs' harmful side effects with no proven benefit. Marketing and prescribing these drugs to mild/moderately manic patients is, in effect, off label.

25. There are no clinical trial results showing efficacy for these drugs amongst this patient population. By masking the lack of efficacy, Merck, J&J, Pfizer and Lilly, atypical antipsychotic manufacturers, are causing false claims to be paid by federal and state health care programs.

II. FEDERAL JURISDICTION AND VENUE

26. This Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732 (a), as well as under 28 U.S.C. §§ 1331 and 1345. The acts proscribed by 31 U.S.C. § 3729 *et seq*. and complained of herein occurred in the District of Massachusetts and elsewhere, as Defendants conduct business in the District of Massachusetts and throughout the United States. Therefore, this Court has supplemental jurisdiction over this case for the claims brought on behalf of the states pursuant to 31 U.S.C. §3732(b) and/or 28 U.S.C. § 1367, inasmuch as recovery is sought on behalf of said states which arises from the same transactions and occurrences as the claims brought on behalf of the United States.

27. This Court has personal jurisdiction over defendants Merck, J&J, Pfizer and Lilly pursuant 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and

because defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside, or transact or have transacted business in this District.

28. The facts and circumstances alleged in this Complaint have not been publicly disclosed in a criminal, civil or administrative hearing, nor in any congressional, or government accounting office report, hearing, audit investigation, or in the news media.

29. Some of the facts and circumstances alleged in this complaint have been publicly disclosed in a drug review posted on the FDA website, and on the internet, however Relator is the author and an "original source" of the review and the information upon which this complaint is based, as that term is used in the False Claims Act.

III. PARTIES

30. The United States funds the provision of medical care, including prescription medications for psychiatric/psychological illnesses, for eligible citizens through Government Healthcare Programs such as Medicare, Medicaid, Federal Employees' Health Benefits Program, TRICARE/CHAMPUS, CHAMPVA, and other agencies and programs, acting through the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human Services ("HHS"), the Department of Defense, and other federal agencies. The FDA regulates the production and manufacturing of pharmaceuticals, including Merck's Saphris® product which is sold in interstate commerce.

31. Relator worked for more than ten years for the Food and Drug Administration (FDA). He has a Bachelor of Science in Pharmacy, Pharm.D., and Ph.D., and served as a Reviewer in clinical pharmacology for the Food and Drug Administration (FDA). As a Senior Reviewer for the Office of Clinical Pharmacology reviewing drugs submitted to the Division of

Psychiatry Drug Products, Relator discovered that several atypical antipsychotic medications had been improperly marketed to patients diagnosed with mild to moderate mania.

32. At times material hereto Merck is and was under a five-year Corporate Integrity Agreement with the Government entered into on or about February 5, 2008.[1]

33. Merck & Co., Inc. ("Merck") came to the United States in 1891 although it was founded in Germany as E. Merck in 1668.[2] In 2009 Merck combined with Schering-Plough under the name Merck & Co. Merck is a New Jersey corporation with its principal place of doing business located at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. For 2011, Merck's gross sales were 48 billion dollars, and profits were in the billions of dollars. For the second quarter of 2012, Merck's worldwide sales increased 5 per cent over 2011 for a total of approximately more than $12.3 billion dollars.

34. Merck has a lengthy history of False Claims Act violations and consumer fraud. These include:

a. On or about December 11, 2011, Merck and its generic drug subsidiary, Warrick Pharmaceuticals Corporation, agreed to pay Massachusetts $24 million to settle a False Claims Act lawsuit accusing Merck and other companies of knowingly reporting inflated prices to industry price reporting services between 1995 and 2003. The lawsuit alleged that Merck (f/k/a Schering-Plough Corporation), its wholly-owned subsidiary, Schering Corporation, and Warrick reported false and inflated prices for three albuterol products;[3]

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[1] This agreement is attached hereto as Exhibit 1.

[2] http://www.merck.com/about/our-history/home.html

[3] http://www.contractormisconduct.org/ass/contractors/139/cases/1764/2634/merck-ma-inflated-drug-prices_agpr.pdf

b. On or about October 6, 2010, the state of Hawaii settled with dozens of pharmaceutical companies, including Merck, accused of gouging Hawaii's Medicaid program for more than a decade by fraudulently inflating their prescription drug prices. The total amount of the settlements was $82.7 million;[4]

c. In November, 2011, Merck, Sharp & Dohme (MSD) [the overseas operating company for the pharmaceutical business conducted in the United States by Merck & Co., Inc.] agreed to pay $950 million to resolve criminal and civil claims related to its promotion and marketing of Vioxx. MSD agreed to plead guilty to a single misdemeanor violation of the Food Drug and Cosmetic Act (FDCA) and pay a $321,636,000 criminal fine. MSD also entered into a civil settlement agreement to pay $628,364,000 to resolve additional allegations regarding off-label marketing of Vioxx and false statements about the drug's cardiovascular safety. The criminal plea related to the misbranding of Vioxx between May 1999 and April 2002 by promoting the drug for treating rheumatoid arthritis before that use was approved by the Food and Drug Administration (FDA);[5]

d. In February 2012, Merck settled a claim by the State of Louisiana against it and other companies for Medicaid fraud relating to Average Wholesale Prices intended to increase wholesale prices;[6]

e. In February of 2008 Merck was accused of violating the Medicaid Rebate Statute in marketing its cholesterol drug Zocor, its prescription pain medication Vioxx, and its anti-heartburn drug Pepcid. Merck allegedly offered hospitals large discounts for all three products if hospitals used them instead of competitors' brands. Merck did not offer similar discounts to Medicaid. Merck was also alleged to have lured physicians into using its

[4] http://www.contractormisconduct.org/ass/contractors/139/cases/1515/2190/glaxo-et-al-hawaii-awp_hipr.pdf

[5] http://www.contractormisconduct.org/ass/contractors/139/cases/1727/2560/doj.pdf

[6] http://www.contractormisconduct.org/ass/contractors/139/cases/1758/2622/glaxo-et-al-defrauding-la-medicaid_laagpr.pdf

products through the payment of illegal kickbacks. Merck agreed to pay more than $650 million to settle the allegations, brought in two separate False Claims Act lawsuits. Merck also entered into a five-year corporate integrity agreement with the Department of Health and Human Services Office of Inspector General;[7]

f. On or about October 23, 2006, Merck's pharmacy benefits company Medco (from which it separated in 2003) settled two False Claims Act cases by paying $137.5 million for allegedly cheating federal employees' health plans through various fraudulent practices involving the processing of mail order prescriptions;[8]

35. Schering-Plough has a history of off label marketing and other False Claims action violations. Illustrative are the following cases:

a. Schering-Plough entered into a Consent Decree with the FDA in 2002 and paid five-hundred million dollars in fines for its manufacturing issues related to its Albuteral inhalers and a number of other products;[9]

b. In December 2009, Schering-Plough agreed to pay $69,000,000 to settle a False Claims Act case brought by Ven-A-Care for the United States and the State of California;[10]

c. In August 2004, Schering-Plough's sales arm, Schering Sales Corporation, pleaded guilty to violating the Anti-Kickback Act and paid a fine of $52.5 million in connection with the illegal and fraudulent pricing of its allergy drug, Claritin;

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[7] http://www.contractormisconduct.org/ass/contractors/139/cases/854/1111/merck-nominal-pricing_dojpr.pdf

[8] http://www.contractormisconduct.org/ass/contractors/139/cases/778/900/merck-piacentile_settlement.pdf

[9] http://www.contractormisconduct.org/ass/contractors/178/cases/1260/1791/schering-plough-2002-fda-consent-decree_consdec.pdf

[10] http://www.contractormisconduct.org/ass/contractors/178/cases/1261/1793/schering-plough-albuterol_settlement.pdf

d. In 2006 Schering-Plough agreed to pay more than $435,000,000 (including the $180,000,000 criminal penalty) for illegal sales and marketing of Temodar® for brain cancer and Intron A® for specific bladder cancer and hepatitis C. This sum included criminal and civil penalties[11] and the allegations included illegal physician kickbacks;

e. Schering-Plough agreed to pay more than $292 million to resolve civil False Claims Act liabilities in connection with the illegal and fraudulent pricing of its allergy drug, Claritin. Schering-Plough subsidiary Schering Sales Corp. pleaded guilty to violating the Anti-Kickback Act in the same matter.

Schering-Plough has settled other *Qui Tam* actions in favor of the States of Texas[12] and Missouri for tens of millions of dollars.

36. Merck merged with Schering-Plough in 2009. Schering-Plough also has historical roots to Germany where it began as Schering, AG. It was a United States company as early as 1851. In 1971 Schering, Corp. merged with Plough, an American company created in 1903 to become Schering-Plough.[13]

37. Organon was a human pharmaceutical company headquartered in Oss, Netherlands. In November 2007 Schering-Plough Corporation acquired Organon.

38. AzkoNobel, N.V. is a multi-billion dollar global industrial company employing more than 57,000 employees worldwide. Its primary business is chemicals and paints and owns and manufactures Glidden paints. It owned Organon until it sold the company to Schering-Plough for more than $14 billion in March of 2007.

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[11] http://www.contractormisconduct.org/ass/contractors/178/cases/1264/1796/schering-plough-_pr.pdf

[12] http://www.contractormisconduct.org/ass/contractors/178/cases/1270/1801/schering-plough-texas-medicaid_pr.pdf

[13] http://en.wikipedia.org/wiki/Schering-Plough; http://www.drugs.com/manufacturer/schering-plough-128.html

39. Pfizer, Inc., is an American company founded in New York, in 1849. Although it is incorporated in Delaware, its world headquarters is in New York City, New York. Pfizer also has paid enormous fines in the past for alleged False Claims Acts violations including off-label marketing including one billion dollars in 2009.[14]

40. Johnson & Johnson is a New Jersey corporation with its principal place of doing business in New Brunswick, NJ. J&J has also allegedly been involved in off-label marketing schemes in recent years resulting in the payment of hundreds of millions of dollars in fines.[15]

41. Eli Lilly & Company is an Indiana corporation with its principal place of doing business in Indianapolis, Indiana. Lilly has also allegedly been involved in off-label marketing schemes in recent years resulting in the payment of over one billion dollars in fines.[16]

IV. INDIVIDUAL PARTICIPANTS

42. Dr. Thomas Laughren, Director of the Division of Psychiatry Products, Center for Drug Evaluation and Research (CDER), Food and Drug Administration.

43. Medical Officer, Dr. Robert Levin of the Division of Psychiatry Products, CDER, Food and Drug Administration.

44. Mr. Keith Kiedrow, Project Manager Division of Psychiatry Drug Products.

45. Dr. Yeh-Fong Chen, Biostatistician.

46. Dr. George Kordzakhia, Biostatistician.

47. Peiling Yang, Ph.D., Biostatistician.

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[14] The 2009 settlement included marketing practices related to Geodon® but unrelated to the issues alleged in this Complaint.

[15] http://www.lexisnexis.com/community/litigationresourcecenter/blogs/litigationblog/archive/2012/06/11/johnson-amp-johnson-reserves-600m-to-settle-risperdal-invega-natrecor-civil-cases.aspx

[16] http://www.forbes.com/sites/erikakelton/2012/05/10/more-pharma-companies-to-join-the-dishonor-roll-pay-billions-for-fraud-following-abbotts-settlement/

48. H. M. James Hung, Ph.D., Biostatistician.

49. Dr. Gwen Zornberg, Team Leader Division of Psychiatry Drug Products.

50. Dr. Mitch Mathis, Deputy Director, Division of Psychiatry Drug Products.

51. Dr. Elzbieta Chalecka-Franaszek, Pharmacology/Toxicology Reviewer Psychiatry Drugs.

52. Dr. Barry Rosloff, Team Leader Pharmacology/Toxicology Psychiatry Drugs.

53. Dr. Andre Jackson, Reviewer Office of Clinical Pharmacology.

54. Dr. John Duan, Reviewer Office of Clinical Pharmacology.

55. Dr. Raman Baweja, Team leader, Clinical Pharmacology.

56. Dr. Ramana Uppoor, Associate Director Division of Clinical Pharmacology 1.

57. Dr. Mehul Mehta, Director Division of Clinical Pharmacology 1.

58. Dr. Joga Gobburu, Director Division of Pharmacometrics.

59. Dr. Shiew Mei Huang, Associate Director Office of Clinical Pharmacology.

60. Dr. Larry Lesko, Director Office of Clinical Pharmacology.

61. Dr. ShaAvhree Buckman, Director, Office of Translational Science (CDER).

62. Jacquita Johnson-House, Lead Program Analyst.

63. Dr. Christine Garnett, Pharmacometrician – Clinical Pharmacology.

64. Dr. Pravin Jadhav, Reviewer Clinical Pharmacology.

65. Dr. Joanne Zhang, Biometrics Reviewer.

66. Dr. Yunfan Deng, Biometrics Reviewer.

67. Dr. Suchitra Balakrishnan, Medical Reviewer – Cardiology.

68. Dr. Norm Stockbridge, Director Division of Cardiovascular and Renal Products.

69. Dr. Ellis Ungar, Deputy Director of the Office of Medical Policy (CDER).

70. Dr. Robert Temple, Director of the Office of Medical Policy (CDER).

71. Jane Axelrad, Associate Director, Office of Regulatory Policy (*CDER*).

72. Virginia Behr, FDA Ombudsman.

73. Dr. Janet Woodcock, Director Center for Drug Evaluation and Research.

74. William McConagha, Assistant Commissioner for Accountability and Integrity.

75. Dr. Eric Von Eschenbach, FDA Commissioner.

76. Dr. Douglas Throckmorton, Deputy Director CDER.

77. Alexandra Meighan, Office of the General Counsel.

78. Bonita V. White, Director, Division of EEO Compliance.

79. Michael Watson, Director, Rockville Human Resource Center.

80. Saundra E. Anderson, EEO Specialist.

81. Graham Jackson, Merck/Schering-Plough's Cardiology Consultant

82. Larry Alphs, M.D., Vice President, Pfizer.

83. Robert Kowalski, Pharm.D., Vice President, Global Regulatory Affairs Schering-Plough Corporation.

84. Armin Szegedi, M.D., Ph.D., Vice President, Global Clinical Research CNS Schering-Plough Corporation.

85. Paul van Hoek, M.D., Medical Safety Adviser, Global Pharmacovigilance Schering-Plough Corporation.

V. THE FALSE CLAIMS ACT

86. The False Claims Act (hereinafter referred to as "FCA" or "the Act"), 31 USC § 3729, was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986

amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government fraud to disclose the information without fear of reprisal or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf. The FCA was further amended in May 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA") and again in March 2010 by the Patient Protection and Affordable Care Act ("PPACA"). Both FERA and PPACA made a number of procedural and substantive changes to the FCA in an attempt to ease the government and private Relators' burdens in investigating and prosecuting *qui tam* suits under the FCA.

88. The FCA provides that any person who knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim is liable for a civil penalty ranging from $5,000 up to $10,000 (and adjusted upward for inflation) for each such claim, plus three times the amount of the damages sustained by the federal government.

89. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendants during that time). Based on these provisions, *qui tam* plaintiff/relator seeks through this action to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

VI. FEDERAL HEALTH CARE PROGRAMS

90. In 1965, Congress enacted Title XVIII of the Social Security Act (known as "Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care. Entitlement to Medicare is based on age, disability or affliction with certain diseases. See 42 U.S.C. §1395 to 1395ccc. Outpatient prescription drugs are covered under Parts A-D of the Medicare Program.

91. In 1965, the federal government also enacted the Medicaid program. It is a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation ("FFP"). Outpatient prescription drugs are covered under the Medicaid Program as long as they meet the definition of a "Covered Outpatient Drug."

92. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10 U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted for outpatient prescription drugs.

93. Pharmaceutical drugs are also used on an inpatient basis, purchased by nursing homes, hospitals, and other facilities for inpatients. Generally, in such settings, the provider does not separately bill the Government Healthcare Programs for the drug; rather, the provider is reimbursed based upon a composite rate, a daily rate, the actual cost, or a combination. Even so, federally funded Government Healthcare Programs such as Medicare Part A, Medicaid inpatient, and TRICARE inpatient benefit are damaged when they pay for pharmaceuticals that have been paid for in violation of the FCA.

94. Under the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), there is an express fundamental condition of payment: "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury." This condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." Medicaid, TRICARE and other federally funded programs restrict coverage under the same principle.

95. Hospitals and other inpatient facilities participating in the Medicare, Medicaid and other federally funded Government Healthcare programs are required to file annual cost reports with the appropriate agencies. When a provider submits a Medicaid cost report which includes requests for payment for pharmaceuticals that were not reasonable and necessary, the claims for those expenses are legally false.

VII. THE FOOD, DRUG AND COSMETIC ACT AND ITS POST MARKETING SAFETY REPORTING REGULATIONS

96. The Food and Drug Administration ("FDA") is the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that pharmaceuticals designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law. Toward this end, FDA, pursuant to its

statutory mandate, regulates and monitors the approval, manufacture, processing, packing, labeling, and shipment in interstate commerce of pharmaceuticals.

97. To ensure that consumers are receiving safe and effective drugs, Congress, through various amendments, enacted the Food, Drug, and Cosmetic Act, which requires that a drug manufacturer secure approval of a New Drug Application from the FDA before it may commercially market the drug. 21 U.S.C. §355(a). To obtain such approval, the manufacturer must undertake to conduct, and submit the results of, investigations in animals and humans that demonstrate that the drug is safe and effective for its intended uses and other information pertinent to an evaluation of the safety and effectiveness of the drug. 21 U.S.C. §355; see also 21 C.F.R. §314.50 (detailing contents of NDA). According to the statutory scheme, the FDA evaluates the safety and effectiveness of the drug and approves the directions for use and cautionary information in the labeling for the drug on the basis of the information supplied to it by the manufacturer. The FDA does not conduct its own tests of the drug. It relies on the manufacturer to inform it of methods, results of experiments and studies, and adverse reaction reports. Thus, the FDA's ability to evaluate a drug's safety and efficacy and to protect the public adequately depends on the manufacturer's reports of timely, accurate, reasonable, and complete data to the FDA.

98. In order to effectuate the legislative goals of the FDA it has promulgated regulations concerning efficacy of the drugs submitted for approval. *See* 21 C.F.R.§ 505(d)(5) (grounds for refusing a new drug application include "a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.") Moreover, failing to include information in the labeling concerning lack of efficacy in known patient populations, lack of or

inaccurate reports of adverse events and how to manage these events, and inaccurate drug information is misleading and constitutes misbranding.

99. Laws and regulations have also been promulgated concerning the safety of drugs submitted for approval. *See* 21 C.F.R.§ 505(d) (grounds for refusing a new drug application include (1) "the investigations … do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling"; (2) "the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions"; (4) "upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions.") Moreover, failing to include information in the labeling concerning lack of efficacy in known patient populations, lack of or inaccurate reports of adverse events and how to manage these events, and inaccurate drug information is misleading and constitutes misbranding.

100. Saphris® was introduced by Merck/Schering-Plough into interstate commerce in violation of the FDCA. *See* 21 C.F.R. §301(a) ("Introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded" is "prohibited").

101. Geodon® was introduced by Pfizer into interstate commerce in violation of the FDCA. *See* 21 C.F.R. §301(a).

102. Risperdal® was introduced by J&J into interstate commerce in violation of the FDCA. *See* 21 C.F.R. §301(a).

103. Zyprexa® was introduced by Lilly into interstate commerce in violation of the FDCA. *See* 21 C.F.R. §301(a).

VIII. SUBSTANTIVE ALLEGATIONS

104. There are serious health risks associated with prescription drugs whose sponsors fail to abide by FDA's requirements. This risk becomes even more poignant when taking into account the fact that approximately eighty percent of drug spending in Government Healthcare Programs is for elderly and disabled enrollees, who have extensive health care needs. In addition, any patient who has taken an ineffective drug is likely to require additional laboratory tests and physician visits, thereby causing additional unnecessary increased costs to Government Healthcare Program.

A. Saphris® Defects

105. Notwithstanding, Merck proceeded to market this dangerous, ineffective drug.

106. The original sponsor of the New Drug Application (NDA) for Saphris® (asenapine) was Schering-Plough.

107. Merck bought Schering-Plough after Saphris® was approved. Although Schering was the sponsor of the New Drug Application, the original developer of asenapine was Organon, which was a subsidiary of Azko Nobel, and Organon was acquired by Schering-Plough which expected Organon's five late-stage compounds, including Saphris®, to generate substantial income.

108. Organon also encountered safety issues with asenapine early in development of Saphris® and entered into a co-development agreement with Pfizer.

109. Pfizer had been the sponsor of the Investigational New Drug file (IND) in the United States and had done all the phase IIB and III clinical development as well as most of the phase I trials and preclinical development.

110. Pfizer failed to comply with FDA mandates of providing notification of serious adverse reactions regarding Saphris®.

111. After completing the phase III studies, Saphris® (asenapine) was dropped by Pfizer when pre-market clinical trials showed Saphris® lacked efficacy and had an excess of cardiovascular and other lethal adverse effects.

112. Pfizer was in a position to drop the drug because it had a comparable drug, Geodon®, approved by the FDA.

113. Pfizer lost hundreds of millions of dollars as a result of its investment in studying Saphris®.

114. Schering-Plough and Merck improperly whitewashed Saphris®' problems to gain marketing approval.

115. Schering-Plough obtained approval of Saphris® through fraudulent means in violation of the Food, Drug and Cosmetic Act (FDCA).

116. Defendant Merck (Schering-Plough) accomplished this by:

a. Providing false and fraudulent information to the FDA;

b. Withholding from the FDA critical information required by law (including safety information) that was necessary for review and approval;

c. Failing to perform studies required by the Food, Drug and Cosmetic Act;

d. Providing misleading information to the FDA on the safety of Saphris®; and

e. Colluding with FDA officials.

117. Merck (Schering-Plough) knowingly misbranded Saphris® and introduced it into interstate commerce in violation of the Food, Drug and Cosmetic Act.

B. Geodon® Defects

118. Pfizer has continued to market this dangerous, ineffective drug, knowing the defects it shares with Saphris®.

119. Pfizer knew of these safety issues with this class of drugs through the testing of Geodon® but also had additional insight early in the development of Saphris®.

120. Pfizer had been the sponsor of the Investigational New Drug file (IND) in the United States and had done all the phase IIB and III clinical development as well as most of the phase I trials and preclinical development for Saphris®.

121. After completing the phase III studies, Saphris® (asenapine) was dropped by Pfizer when pre-market clinical trials showed Saphris® lacked efficacy and had an excess of cardiovascular and other lethal adverse effects. Pfizer failed to utilize this information to prevent similar dangers to users of Geodon®.

122. Pfizer was in a position to drop the drug because it had a comparable drug, Geodon®, approved by the FDA.

123. Pfizer obtained approval of Geodon® through fraudulent means in violation of the Food, Drug and Cosmetic Act (FDCA).

124. Defendant Pfizer accomplished this by:

a. Providing false and fraudulent information to the FDA;

b. Withholding from the FDA critical information required by law (including safety information) that was necessary for review and approval;

c. Failing to perform studies required by the Food, Drug and Cosmetic Act;

d. Providing misleading information to the FDA on the safety of Geodon®; and

e. Colluding with FDA officials.

125. Pfizer knowingly misbranded Geodon® and introduced it into interstate commerce in violation of the Food, Drug and Cosmetic Act.

C. Risperdal® Defects

126. J&J has continued to market Risperdal®, a dangerous and ineffective drug, knowing the defects it shares with Invega®.

127. J&J knew of the lack of efficacy and safety issues with this class of drugs through the testing of Invega® (paliperidone, also known as 9-hydroxy-risperidone or 9-OH-risperidone). Since J&J claims that 9-OH-risperidone is equipotent at binding to receptors that are responsible for Risperdal®'s therapeutic effects, and since studies and analyses performed by J&J showed that Invega® does not work in patients with mild or moderate mania, but does work in severe mania in bipolar I disorder, J&J had sufficient information to establish that Risperdal® did not work for patients with mild or moderate mania either.

128. J&J obtained approval of Risperdal® through fraudulent means in violation of the Food, Drug and Cosmetic Act (FDCA). It failed to comply with FDA mandates of providing notification of further adverse reaction reports.

129. Defendant J&J accomplished this by:

a. Providing false and fraudulent information to the FDA;

b. Withholding from the FDA critical information required by law (including safety information) that was necessary for review and approval;

c. Failing to perform studies required by the Food, Drug and Cosmetic Act;

d. Providing misleading information to the FDA on the safety of Risperdal®; and

e. Colluding with FDA officials.

130. J&J knowingly misbranded Risperdal® and introduced it into interstate commerce in violation of the Food, Drug and Cosmetic Act.

D. Zyprexa® Defects

131. Lilly has continued to market this dangerous, ineffective drug, knowing the defects it shares with Saphris®.

132. Lilly knew of the safety issues with this class of drugs through the testing of Zyprexa®.

133. Lilly obtained approval of Zyprexa® through fraudulent means in violation of the Food, Drug and Cosmetic Act (FDCA). It failed to comply with FDA mandates of providing notification of further adverse reaction reports.

134. Defendant Lilly accomplished this by:

a. Providing false and fraudulent information to the FDA;

b. Withholding from the FDA critical information required by law (including safety information) that was necessary for review and approval;

c. Failing to perform studies required by the Food, Drug and Cosmetic Act;

d. Providing misleading information to the FDA on the safety of Zyprexa®; and

e. Colluding with FDA officials.

135. Lilly knowingly misbranded Zyprexa® and introduced it into interstate commerce in violation of the Food, Drug and Cosmetic Act.

E. Saphris®, Geodon®, Risperdal®, and Zyprexa®' Lack of Efficacy – Bipolar I Disorder

136. Merck (Shering-Plough), Pfizer, J&J, and Lilly obtained approval for Saphris®, Geodon®, Risperdal®, and Zyprexa® for acute manic and mixed manic/depressive episodes in patients with Bipolar I Disorder.

137. Merck/Schering's data shows that Saphris®' efficacy is dependent upon the severity of the manic episode, with only the sickest 50% or so of patients for whom it is approved experiencing a significant positive response.

138. Pfizer, J&J, and Lilly have similar data and study results for Geodon®, Risperdal®, and Zyprexa®.

139. Consequently, one-half (50%) of all patients with Bipolar I Disorder have **no** possibility of benefit from Saphris®, Geodon®, Risperdal®, or Zyprexa® yet these drugs are prescribed to mild and moderately ill manic patients anyway with significant risk of serious toxicities, including death.

140. As a class effect, the total amount of fraud in the prescribing and sales of antipsychotics including Saphris®, Geodon®, Risperdal® and Zyprexa® may be well be in the billions of dollars *per year*.

141. There are 2 million adults in the US with Bipolar I Disorder. Of these 50% are treated. If 50% of the treated patients have no chance of receiving benefit from the drugs based on the severity of their illness, then 500,000 individuals in the US are being subjected to toxicities unnecessarily. The mortality rates in antipsychotic drug development programs are consistently around 1% – 1.2% with most deaths occurring with longer use, thus the true mortality rate in practice is likely much higher. Even using these rates from the drug development programs results in an estimated 5000 – 6000 preventable deaths annually in the

US. Not to mention the numerous other serious adverse effects that occur with antipsychotics including seizures, blood clots, heart attacks, diabetes, neurologic toxicities etc.

142. Relative to Saphris® itself, two three-week efficacy studies were performed on Bipolar I patients. These studies evaluated efficacy only in acutely manic or mixed manic hospitalized patients.

143. There are various degrees of elevated mood that occur with various mood disorders. Bipolar I disorder includes patients who are fully manic and need to be hospitalized, as well as patients who are hypermanic, i.e. the most severely ill including those who are psychotic (i.e. hallucinating and having delusions). Historically, antipsychotic drugs were used in hypermanic psychotic patients to control psychotic symptoms.

144. In contrast, Saphris® was not studied in patients with Bipolar II Disorder and, in fact, no drug is approved for use with Bipolar II disorder. Bipolar II disorder includes patients who are hypomanic, which can be a very pleasurable experience with elevated mood, increased energy, and increased productivity.

145. Based upon his experience with the limitations of clinical trials for drugs for the treatment of depression (a mood disorder like bipolar disease) and knowledge of the basis for the historical use of antipsychotics in this population, Dr. Kavanagh while employed by the FDA and assigned to the application for this drug, decided to look at whether the efficacy of Saphris® was dependent upon the severity of the manic episode.

146. Dr. Kavanagh combined data from two studies submitted to the FDA by Defendants. He divided the different treatments (placebo, Saphris® and Zyprexa®) into quintiles based on the severity of the episode using the Young Mania Rating Score (YMRS).

147. Dr. Kavanagh found that there was **no** identifiable response in the two least severely ill quintiles. **In fact, the response curves for the drugs were identical to the response curves for placebo when the curves were overlaid.**

148. The two quintiles identified by Relator Kavanagh included all bipolar I patients with YMRS scores of 18-26 and represented 40% of all patients for which Saphris® was eventually approved and for which Zyprexa® had already been approved.

149. In contrast, Dr. Kavanagh found that there was a clear effect with the more severely ill patients, as demonstrated by the separation of the average response over time to Saphris® and Zyprexa® compared with the average response over time to placebo. This separation in response became more pronounced with the severity of the illness as assessed by the Young's Mania Rating Scale.

150. The positive response amongst Saphris® patients in the quintiles of more severely ill patients elevated the apparent efficacy scores for less severely ill patients when the data from all patients were combined and the combined effect was compared with the effect seen with placebo.

151. Dr. Kavanagh, with years of education and over a decade with the FDA concluded that Saphris®' approval and labeling were based on the misleading results when mild and moderately ill patients' mania scores are combined with the more severely ill quintiles' scores, resulting in Saphris®' inappropriate approval for all five quintiles of illness severity, not just the three quintiles for whom improvement was demonstrated.

152. When the various quintiles are separated, a large portion of the manic patient population for whom Saphris®, Geodon® and Zyprexa® are indicated for have no more efficacy than placebo.

153. By manipulating the test population, Merck/Schering-Plough obtained overall approval for Saphris®, substantially increasing the populations to whom marketing efforts could be targeted, leading to prescriptions of expensive but ineffective antipsychotic treatments to less severely ill manic patients.

154. Similar manipulation by Pfizer, Johnson and Johnson, and Lilly resulted in approval for Geodon®, Risperdal®, and Zyprexa®, substantially increasing the populations to whom marketing efforts could be targeted, leading to prescriptions of expensive but ineffective antipsychotic treatments to less severely ill manic patients.

155. This combining of patients with different severity of illness failed to result in a positive study with Invega® (9-hydroxy-risperidone), a metabolite of Risperdal® (risperidone). However, Johnson and Johnson's own analysis showed that efficacy was only demonstrated in the sickest manic subjects with Bipolar I Disorder, i.e. patients with a Young's Mania Rating Score of greater than or equal to 30. Whereas mania in Bipolar I Disorder may include patients with scores as low as 18. Since Johnson & Johnson claims that risperidone (Risperdal®) and 9-hydroxy-risperidone (Invega®) have the same effects, the company was thus aware of the effect of an expansive population on the labeling for Risperdal®.

156. Each prescription for Saphris®, Geodon®, Risperdal®, and Zyprexa® for the lower quintile patients, paid for by federal and state health care programs, was based upon fraudulent representations as to their effectiveness by Defendants, resulting in false claims being paid.

157. Relator Kavanagh also reviewed the statistical analysis of Saphris®' "drug response over time" submitted to the FDA by Merck/Schering. This analysis also utilized the data combined from both studies but did not examine the effect of the severity of the manic

episode. When the data was examined, the average and median response curves were different, particularly when they are compared to the placebo curves. This indicated that any apparent positive drug treatment response is likely varying with severity and that further analysis was needed. However, no such further and additional analysis was undertaken by the company, or if it was performed, it was not submitted to the FDA.

158. In order to fully evaluate these findings, Dr. Kavanagh checked the FDA files and was able to gather data on Geodon® and Zyprexa®, other antipsychotic drugs which he hoped to use for comparative analysis. When Dr. Kavanagh analyzed these other antipsychotics, he obtained results similar to his findings as to the lack of efficacy in less severely affected patients as Saphris®. Data from other antipsychotics were not examined as data was no longer readily available.

159. One of the other drugs Dr. Kavanagh analyzed was Pfizer's drug, Geodon® (ziprasidone). Relator found an FDA statistical report from approximately 2002 which indicated there was a relationship between disease severity and efficacy of the drug.[17]

160. A reading of the FDA files resulted in Relator concluding that the FDA failed to look into the issue for any other atypical antipsychotic, including Zyprexa® even though the same statistical reviewer completed virtually every other statistical analysis of atypical antipsychotics for mania, including Saphris®. While at the same time hiding similar findings by Johnson and Johnson for their antipsychotic Invega® and the implications it had for Risperdal®.

161. Close to the date Dr. Kavanagh was scheduled to complete the Saphris® review, another company, Johnson and Johnson, asked to meet with the FDA to discuss whether the FDA would approve its antipsychotic Invega® (9-OH-risperidone) in patients with Bipolar I

[17] Despite this, no follow-up was conducted on this issue.

Disorder with YMRS scores of greater than 30 (i.e., in the more severely ill population only). The company requested this because the overall study of its antipsychotic was negative, but the company's analysis showed the drug was effective for the more severely ill patients whereas the less severely ill patients did not show a response.

162. With the meeting scheduled with the company described in the paragraphs above approaching, and within the time frame when reviewers generally start preparing for meetings, Dr. Kavanagh's management suddenly removed him from the review and reassigned it to another FDA employee.

163. Dr. Kavanagh was given no explanation for being removed from the investigation.

164. Relator states that in his opinion, the totality of these findings indicates that atypical antipsychotic efficacy is based on severity of the illness and is a class effect. Thus, approximately 50% of the patients for whom Saphris®, Geodon®, Zyprexa® and Risperdal® are approved do not obtain any benefit.

165. Merck, Pfizer, J&J and Lilly knew and know that by properly labeling Saphris®, Geodon®, Risperdal® and Zyprexa®, patients who are unlikely to respond could and can be predicted *before* beginning treatment and thus lethal toxicities could and can be avoided.

166. The results of the efficacy analysis by severity was provided to Merck/Schering-Plough prior to FDA approval, and was available to all other antipsychotic marketers.

167. Knowing that Saphris® had limited or no efficacy for a large portion of the manic patient population for whom Saphris® had been submitted, Merck/Schering proceeded with securing marketing approval notwithstanding the lack of efficacy.

168. The FDA uncharacteristically asked Merck/Schering for a post-marketing efficacy study in Bipolar I Disorder. However, ClinicalTrials.gov indicates that conduct of such a study is not presently anticipated, even though other FDA-requested studies, with due dates several years in the future, are already underway.

169. To Relator's knowledge, the FDA had never previously requested a post-marketing efficacy study in Bipolar I, suggesting the agency has begun to question the efficacy trials and representations.

170. The approval and marketing of Saphris®, Geodon®, Risperdal®, and Zyprexa® is in direct violation of the Food, Drug and Cosmetic Act because based on the information available for Saphris®, along with the similar information for Zyprexa®, Geodon® and Invega®, there is a lack of substantial evidence the drug will have the effects represented in approximately half of Bipolar I patients. *See* 21 C.F.R.§ 505(d)(5) (grounds for refusing a new drug application include "a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.") Moreover, failing to include information in the labeling concerning lack of efficacy for mild/moderately ill manic patients and instead clearly indicating the drug is approved for <u>all</u> bipolar I patients is misleading and constitutes misbranding.

171. The approval and marketing of Saphris®, Geodon®, Risperdal® and Zyprexa® is in direct violation of the Food, Drug and Cosmetic Act because based on a lack of efficacy any of the known adverse effects make the drugs unacceptably unsafe. *See* 21 C.F.R.§ 505(d) (grounds for refusing a new drug application include (2) "the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under

such conditions"; (4) "upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions.") Moreover, failing to include information in the labeling concerning lack of efficacy in known patient populations in the face of adverse effects is misleading and constitutes misbranding with respect to whether the drugs are acceptably safe.

F. Saphris®' Lack of Efficacy – Acute Psychosis in Schizophrenia

172. Saphris® (asenapine) also failed to demonstrate efficacy in acutely psychotic patients with schizophrenia in two adequate and well controlled studies as required by the Food Drug and Cosmetic Act.

173. One study used as a basis for approval did not demonstrate efficacy with the active control arm. This precludes the study being well controlled.

174. This study also had evidence that the different treatment arms enrolled patients with different degrees of severity of the psychotic episode at baseline. Thus the patient populations were not comparable. Comparability of patient populations is required for a well controlled study.

175. The second study demonstrated efficacy for Saphris® with the lower 5 mg dose but not the higher 10 mg dose. This is contrary to expectations since efficacy is more likely to be seen with a higher dose than with a lower dose. Thus casting doubt about the reliability of the study results.

176. However, Merck/Schering created the false appearance of schizophrenia efficacy by manipulating conclusions of the test results conducted on psychotic schizophrenic inpatients.

177. The FDA statistician and an outside statistical expert both raised another issue and both recommended non-approval of Saphris® for use in the treatment of schizophrenia due to improper testing and unreliable results. Specifically, they were concerned that the results were not reliable as the drop-out rate of the study was unacceptably high. Between 60% and 70% of the patients failed to complete the study, thus only 21 to 28 subjects completed the study and were evaluated. Consequently only about 7 subjects had a response with each treatment and thus a single individual with an unusually large spontaneous improvement could change the conclusions. Statistically the results were not reliable and the test sample far too limited to rely upon.

178. Despite the questions raised by the high drop-out rate for study participants and the opinions of the statisticians that they were very uncomfortable with this drop-out rate, pressure was asserted for approval of the medication.

179. There are indications in Pfizer press releases that the company dropped out of co-developing Saphris® and making a submission to the FDA because of these efficacy problems with the schizophrenia trials.

180. The European Union did not approve Saphris® to treat schizophrenia due to questionable efficacy after the EU reviewed the testing described above.

181. In spite of these issues, Merck/Schering-Plough sought and obtained approval for a Saphris® schizophrenia indication.

G. Saphris®' Risks

i. Saphris-Induced Neutropenia and Agranulocytosis

182. Several cases of neutropenia and agranulocytosis (life threatening lowered white blood cell count) were detected during Saphris®' development. Because of Saphris' similarity

to clozapine, whose distribution is restricted due to the risks of neutropenia and agranulocytosis, there was an expectation that similar toxicities might occur with Saphris®.

183. During clinical studies Merck/Schering was monitoring for these toxicities. In fact, two cases occurred during the development of Saphris® where the laboratory data indicated that neutropenia was developing and more frequent blood testing was required. In one case the patient was sent home to continue on Saphris® for an additional 2 months when automated warnings were issued based on low white blood counts along with instructions to notify the sponsor. Rather than stopping the drug as is recommended in FDA labeling for clozapine, dosing with Saphris® was continued and the patient died. Presumably as a consequence of agranulocytosis. This death was not reported to the FDA within 15 days as required by law. The records were found by Dr. Kavanagh buried in documents in the New Drug Application submitted several years later.

184. Upon further investigation Dr. Kavanagh discovered that the sponsor had not only known of the developing neutropenia and death, but, in addition to not reporting it, had asked the FDA for permission to break the study blind, immediately after the automated warning and again immediately after the patient was found dead, apparently to comply with European regulations to determine whether the patient had been receiving Saphris®. The sponsor was allowed to break the blind and it was discovered that the patient had been taking Saphris®. The sponsor also convened a Drug Safety Monitoring Board meeting of external experts to make recommendations about the conduct of the study (whether to continue, discontinue or make changes to the study). However, the sponsor prohibited the Drug Safety Monitoring Board from making recommendations regarding the overall Saphris® development program.

185. The two cases of presumed neutropenia/agranulocytosis, including the case where the patient died as a consequence, were only detectable by laboratory blood tests after the patients had been on Saphris® for 62 weeks. After the first death, the sponsor altered the design of the long term safety study in which the cases had occurred so that safety information would thereafter only be collected up to 52 weeks. The company then requested permission from the FDA not to report post-52 week safety data from this study to the NDA – claiming that the study was ongoing and that the longer-term data would be un-interpretable as there was not a placebo control arm. However, reporting long-term safety data without placebo safety data is actually the standard practice.

186. This study was originally a long-term safety study with no limits on exposure, where patients who had achieved a response to Saphris® in the short-term studies were then allowed to remain on Saphris® long-term to collect safety information.

187. In fact, for drug approval, the standard is six months of long-term data in 500 subjects and one year of such data in 100 subjects which is required by the United States, the European Union, and Japan. No placebo control is required and the data only has to be provided for a marketed dose, so not even for the largest and likely most unsafe dose but only the lowest approved dose. These studies can be either open-ended or truncated after six months or one year. Ideally, it is better to have open-ended studies as cumulative toxicities will be harder to detect when the duration of the safety study is truncated.

188. Thus, the six deaths with Saphris®, including the one possible death due to agranulocytosis, in the 24 patients exposed to Saphris® for more than 17 months is highly significant.

189. Instead of reporting this risk of a cumulative long-term toxicity in the labeling, Merck's labeling indicates that monitoring for developing neutropenia/agranulocytosis is only necessary for a few months. Such labeling is misleading and, based on clozapine data, could result in missing half the cases of agranulocytosis in practice, whereas continued monitoring and detection could prevent deaths. This is highly significant because the data indicates the rate of agranulocytosis is approximately 1 in 150 to 300 people who are taking Saphris® for 18 months or longer.

ii. Anaphylaxis

190. On September 1, 2011, the FDA announced that Saphris® causes severe allergic reactions, including anaphylaxis. Anaphylaxis is a severe life threatening allergic reaction that may cause a swelling of the throat resulting in death by suffocation, or it may cause death by a severe drop in blood pressure resulting in cardiopulmonary arrest.

191. The FDA announcement indicates that the frequency in which this occurs with Saphris® is in at least one in 830 patients.

192. This rate for anaphylaxis and allergic reactions with Saphris® is at least four to five times higher than with the next most common nonbiologic drugs for outpatient use that cause anaphylaxis, the penicillins.

193. Anaphylaxis can occur with the very first dose of Saphris®, probably due to sensitization from other antipsychotics. This is especially problematic as anaphylaxis typically requires prior exposure to the causative agent.

194. Merck/Schering-Plough was aware of at least two cases and possibly three cases of allergic reactions during the development of Saphris® including a death. Merck/Schering knew or should have known that this was a statistically significant number.

195. The case report concerning the death due to an allergic reaction clearly shows it was due to anaphylaxis with no indication of any other possible cause, however, in summary tables, Merck/Schering-Plough reported the death as secondary to a pulmonary embolus.

196. The Relator, Dr. Kavanagh, brought this death due to anaphylaxis to the attention of various FDA officials in both written reports and in an oral presentation with slides, yet his concerns were repeatedly ignored and his superiors simply accepted Merck/ Schering-Plough's knowingly false explanation that the death was attributable to a pulmonary embolus.

197. The only known effective treatment for anaphylaxis and its complications are epinephrine, dopamine, and IV fluids. However, due to the pharmacologic effects of Saphris®, epinephrine and dopamine are contraindicated because the concomitant use of either with Saphris® can cause lethal cardiovascular collapse.

198. Despite having knowledge of these facts, Merck/Schering provided no information on the risk of anaphylaxis in the labeling for the first 22 months Saphris® was on the market. Even when information on anaphylaxis was added, information on the contraindicated use of epinephrine and dopamine with Saphris® was only included under the section on OVERDOSAGE and the labeling regarding anaphylaxis does not note the risk of using epinephrine or dopamine. Nor does it cross reference to the information of the risk of using these agents under the section on OVERDOSAGE. Consequently the labeling section on anaphylaxis continues to be misleading.

199. In addition, Merck/Schering provides no warning information on cross-reactivity with other antipsychotics and consequently the labeling section on anaphylaxis continues to be misleading with regard to this also.

iii. Suicidality

200. There is a combined rate of 1% for both suicidality and completed suicides for Saphris® and Zyprexa® that occurs in the first two to three weeks of treatment for Bipolar I Disorder in clinical studies. In contrast, there were no suicides or suicidality in the patients taking a placebo in these studies.

201. Merck/Schering-Plough has repeatedly dismissed this elevated suicide risk by invalid methods. Specifically they have normalized the risk of suicide over the total length of time patients have been exposed to Saphris®, which may be upwards of 1 year. They then calculated an estimated range for probability based on 100 patient years of use and then compared this to similar calculations based on only 3 weeks of use in patients on placebo. When such methods are used the estimated range for the probability of suicidality occurring with Saphris® includes a 0% chance of suicidality occurring and thus the risk is claimed to be no different than with placebo. This method is inappropriate as comparing 1 year of use to 3 weeks of use is an invalid comparison, especially as the risk of suicidality with Saphris® beyond 3 weeks of use drops precipitously and as most exposure occurs at later than 3 weeks.

202. Two case reports of Saphris® patients with suicidal ideation have been published in the August 2011 issue of the Journal of Clinical Psychopharmacology.

203. Despite the foregoing, Merck/Schering-Plough's Saphris® label misleadingly indicates that suicide is a risk of the underlying illness without any mention of the risk from Saphris®.

iv. Hepatotoxicity

204. Blood tests from clinical studies show evidence of liver toxicity when the sublingual formulation of Saphris® is swallowed, and data from one study indicated the

possibility of severe life threatening liver damage after two weeks of exposure with swallowed dosages only slightly higher than the labeled dosages.

205. The complete laboratory dataset from the safety study that provided information on liver toxicity needed for safety assessment was not submitted to the FDA. The information was never submitted to the FDA by Merck/Schering despite requests for its production. This additional information could have affected a "go – no go decision" on Saphris®.

206. There is no information on the risk of Saphris® being hepatotoxic in the labeling.

v. Liver Disease

207. As a hepatotoxic drug, Saphris® should be contraindicated in anyone with any degree of liver disease because the additional toxicity could kill the person. Labeling for Saphris® only indicates that the dose of Saphris® should be adjusted in severe liver disease because of the effect of the liver disease already present on the exposure to Saphris®, not because of Saphris®' risk of exacerbating any preexisting liver disease.

208. Data shows that Saphris® exposures were also increased in mild and moderate liver disease to a degree such that FDA regulatory standards require dose adjustment even if Saphris® was not hepatotoxic. Instead, there is no recommendation for dose adjustment in patients with mild or moderate hepatic failure.

209. This mislabeling results in false claims for payment for this drug.

vi. Excluded Toxicities

210. Merck/Schering-Plough has avoided including any mention in labeling of several serious toxicities that were observed with the use of asenapine. These observed toxicities include myocardial infarction, cardiac arrest in a young healthy individual, heart failure, as well

as a number of cardiac arrhythmias and conduction disturbances. The effect of Saphris® on bone growth was also excluded from the labeling.

211. In the case of the young healthy individual with cardiac arrest, Merck/Schering-Plough claimed in summary documents that the toxicity was only the patient fainting as a consequence of excess vagal tone.

212. However, Merck/Schering-Plough's own cardiology consultant determined, after examination of the patient and review of the records, that there was no evidence of increased vagal tone and that the repeated cardiac arrests in spite of emergency treatment with antiarrhythmic drugs indicated that the cardiac arrests were due to a direct toxic effect of Saphris® on the heart.

213. Many of these effects are known to occur with clozapine and other azepine antipsychotics and there are clear warnings in the labeling of other drugs such as Zyprexa® and Seroquel®. Thus, they are not unexpected with Saphris® and not including warnings about them in labeling is intentional.

vii. Drug Interactions

214. Many of the drugs listed in the Saphris® label as having been studied for interactions with Saphris® indicate that there are no interactions. For this reason, prescribing physicians have the right to assume that no dosage adjustment is necessary.

215. In addition, during the Psychiatry Advisory Committee meeting on Saphris®, Merck/Schering-Plough stated that there were no pharmacokinetic interactions with certain drugs.

216. These claims, however, ignore the fact that, in interaction studies Merck/ Schering-Plough conducted with Saphris® and these other drugs, in some cases there are

several-fold increases in the exposures to Saphris®' metabolites due to interactions and that these metabolites may cause toxicities.

217. Merck/Schering-Plough continues to fail to provide written warnings concerning these interactions, nor do they provide information to guide dosage adjustment in the labeling.

218. According to Dr. Kavanagh's review, there are also clinically significant interactions of Saphris® with other drugs.

219. Saphris® is extremely potent in causing certain interactions. For example, Saphris® 5 mg BID caused a doubling of exposure to paroxetine due to Saphris®' inhibition of the enzyme CYP2D6. This is highly significant as paroxetine is the most potent known inhibitor of the enzyme being studied and only another extremely potent inhibitor could affect it. These interactions caused significant cardiovascular toxicities with even a single dose of Saphris® (atrial fibrillation and myocardial infarction). Despite these facts, the labeling for Saphris® states that it weakly causes interactions, but "Saphris® should be co-administered cautiously with drugs that are both substrates and inhibitors for CYP2D6."

viii. QT Effect

220. QT effect is a measure of effect on the electrocardiogram that is thought to predict the risk of sudden death from cardiac arrhythmias. This is an issue for all antipsychotics and not having such an effect is a major marketing advantage. Accordingly, there is an international agreement on interpretation under the International Committee on Harmonization to which the FDA is bound. This standard indicates that a drug has a QT effect if the 90% upper limit of any time matched placebo corrected heart rate corrected QT is greater than 10 mSec.

221. Relator has verified that the QT effect value for Saphris® is 17.1 mSec. However, the labeling reports that the QTc is less than 5 mSec which is a value associated with no risk at all of sudden cardiac death.[18]

ix. Lack of Metabolite Information & Possible Phen-Fen Like Effects

222. Dr. Kavanagh was told by a former FDA employee who had previously worked for at least two different drug companies, including Pfizer, that Saphris® metabolites stimulate the 5HT2B serotonin receptor. Stimulation of this receptor by phen-fen is the cause of phen-fen induced pulmonary arterial hypertension and cardiac valve stenosis. The employee also told Dr. Kavanagh that information in Schering-Plough's possession concerning this risk with Saphris® had not been submitted to the FDA. In addition, the former drug company employee indicated that this was also the case for other antipsychotics from other drug companies, including ones he had worked on. A number of pieces of evidence supported his contention, including pharmacology, animal toxicology, and human clinical pharmacology and safety data.

223. Saphris® drug metabolism studies were clearly designed to disguise or hide appropriate information needed to assess the potential for phen-fen like toxicities, including toxicities reported in clinical studies.[19] An article by the Saphris® IND sponsor's scientists showed that Schering-Plough knew the drug metabolism/mass balance study was not reasonable

[18] The 5 mSec value was calculated by Merck/Schering Plough in conjunction with Pfizer based on a linear regression analysis with plasma drug concentrations. This assumes that the effect of the drug is always the same at the same concentration of the drug. This is frequently not a valid assumption because metabolites with cardiac effects may build up and they may be responsible for the QT effect and not the parent drug. Also, it may take time for the drug to diffuse into and out of tissues where the drug causes its effect, or the time course of pharmacodynamic effects may lag due to delayed changes in intermediary pathways. It is for these reasons the ICH specifically avoided allowing the regression analysis on which Merck/Schering Plough relies. For Saphris® there is clear evidence that the regression analysis is likely invalid due to nonlinear metabolite kinetics and their effects.

[19] There were also toxicities observed that might be explained by other pharmacologic effects that such studies would have also revealed, if they had been done.

for the intended purpose.[20] Specifically, the abstract for this paper states that a primary objective for such a study is that it should determine "the drug-related entities present in circulation that are the active principals contributing to primary and secondary pharmacology."

224. It is likely that Merck/Schering-Plough knew and knows the types of chemical structures associated with Saphris®' metabolites are known to cause phen-fen-like effects and that evaluation of such effects would be required.

225. Even so, pharmacologic activity experiments were conducted on only a limited subset of Saphris® metabolites that did not include the ones of most interest, and available information indicated that other unidentified metabolites that were produced should also have been evaluated. Yet, even for the metabolites tested, the reported results did not include the type of information the experiments are known to generate, and this lack of data matched what Dr. Kavanagh had been told (by the former drug company employee) had been withheld by the sponsor.

226. Dr. Kavanagh also detected fraudulent statements in Schering-Plough's New Drug Application for Saphris® related to the mass balance study.[21]

227. These issues were so important and were discovered at such a late date in the review cycle that FDA policy required that they not be communicated to Merck/Schering-Plough

[20] Roffey SJ, Obach RS, Gedge JI, Smith DA. What is the Objective of the Mass Balance Study? A Retrospective Analysis of Data in Animal and Human Excretion Studies Employing Radio-labeled Drugs. Drug Metabolism Reviews, 39: 17- 43, 2007.

[21] Merck/Schering-Plough improperly discussed with FDA management the idea of submitting a response to this issue with timing of the submission to take place after Dr. Kavanagh had been instructed to complete his final review. This communication was undertaken in violation of FDA policy and procedures which prohibit communication of major approval issues immediately prior to when the decision letter is to be issued. No communication on this issue was requested or formulated by the clinical pharmacology review experts in this area who would normally draft specific language and then have it approved. The content of the communication with the company was not documented and only the Psychiatry Division Director, Dr. Laughren, was involved in the discussions with the company.

and that instead Saphris® not be approved and that the issue be addressed in response to the non-approval.

228. In violation of FDA policy, Merck/Schering-Plough was informed of the deficiencies that would normally preclude approval without the required request coming from the relevant consult division (i.e. clinical pharmacology) and Merck/Schering-Plough was allowed to submit a response.

229. This response was discovered by the relator and was found to contain a number of fraudulent statements.

230. FDA policy was then changed so that the review could be extended and a non-approval letter could avoid being sent. A meeting was then granted to Merck/Schering-Plough to discuss the company's mass balance study. Prior to the meeting, Dr. Kavanagh and his team leader discussed the data and fraudulent statements and determined that the company should be asked to explain its fraudulent statements. Immediately after this decision, Dr. Kavanagh was physically removed from the agency and was later terminated specifically for reporting possible crimes related to the review and anticipated approval of Saphris® to the FBI, the HHS Office of the Inspector General, and to Congress. However, after Dr. Kavanagh's removal, his team leader made the inquiry to the company.

231. Schering-Plough responded to the request to explain its questionable statements and as much as admitted to the deception, however, the company's response was dismissed by the FDA, with the FDA stating that the agency did not understand the company's response, but that it was unimportant anyway.[22]

[22] That the response was not understood is not credible. The issue is basic to the evaluation of every generic drug and the reviewer who claimed the response was not understandable was an expert on generic drug evaluation who had worked on generic drug approvals for decades. This

232. However the subsequent reviewers with expertise in the review area agreed with Dr. Kavanagh that certain other types of studies required by the FDCA needed to assess the potential for phen-fen like and other toxic effects had not been provided and that approval should not be granted.

233. Notwithstanding, Merck/Schering continued to push for Saphris®' approval and persuaded FDA management to improperly agree that the issues had been resolved. Thereafter, Merck/ Schering obtained Saphris® approval in violation of the FDCA.

234. FDA approval of Saphris® is not a defense of Merck/Schering-Plough's actions. As the Supreme Court recently made clear, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times" and the manufacturer "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 1187, 1197-1198 (2009).

x. Pulmonary Arterial Hypertension (PAH) and Neonatal Toxicity

235. Based on the potential risk of a phen-fen like toxicity of pulmonary arterial hypertension (PAH), the likely use of a drug for bipolar disorder in pregnant women, and the known risk of other psychiatric drugs that affect the serotonin system to cause neonatal PAH, Dr. Kavanagh immediately went to check the animal reproductive toxicology data.

236. Dr. Kavanagh then found that the animal reproductive toxicology data had been hidden by the pharmacology/toxicology reviewers and upon further investigation found that it included reproductive cross-fostering studies in which animals were exposed to asenapine *in*

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reviewer had testified before Congress regarding the generic drug scandal in the early 1990's, and even prior to Dr. Kavanagh's removal, was terrified of retaliation by FDA management. On other occasions Dr. Kavanagh had noted that he would refuse to make any comment, including regarding review issues, where he was afraid of possible FDA management retaliation.

utero and postnatally via breast milk. Some animals were exposed to asenapine only *in utero*, some only by breast feeding, and some both ways.

237. Results of the cross-fostering studies indicated there was a lethal effect due to asenapine, the active drug in Saphris®, both due to *in utero* exposures and due to exposure by breast feeding, with the highest lethality in animal pups exposed both ways. According to an FDA toxicology team leader, such cross-fostering studies are "*only conducted if the sponsor is looking for something."* It is well known that many antidepressants that affect serotonin receptors, (SSRIs), cause neonatal pulmonary arterial hypertension (PAH) and that many cases of neonatal PAH result in infant deaths. It is also believed that most fatalities due to neonatal PAH are misdiagnosed as sudden infant death syndrome (SIDS). Coincident with the introduction of these drugs (i.e. SSRIs), the rate of SIDS in the United States increased by 50%. Nearly 20 years later, it was finally discovered that the rate of PAH is five-fold higher in neonates exposed to SSRIs *in utero*. Based on this information, Dr. Kavanagh requested that post-marketing safety data from atypical antipsychotics similar to asenapine that affect serotonin receptors be examined, with a request that certain specific antipsychotics be examined. This was requested as a potential imminent danger to the public health since the Secretary of HHS him/herself must make a decision with respect to drug withdrawal from the market under such circumstances.

238. Recently, Dr. Kavanagh has been able to examine this data from publically available FDA data and found evidence that indicates cumulative infant deaths in the first year of life due to atypical antipsychotics to be in the thousands, with deaths due to Seroquel® (quetiapine-AstraZeneca), which is chemically and pharmacologically similar to asenapine, being greatest. These numbers greatly exceed the death rates for neonatal deaths with

antidepressants that are known to cause PAH. These findings are consistent with a class effect on the 5HT2B receptor by atypical antipsychotics including Saphris®, Geodon® and Zyprexa®. Taking into account known underreporting (i.e. typically 1%-10% of cases reported), misdiagnosis of neonatal PAH deaths as SIDS (≥50%), cumulative deaths since marketing began (1985 for SSRIs and 1995 for commonly used atypical antipsychotics), and that this is likely a class effect for all atypical antipsychotics and SSRI antidepressants, the number of infant deaths from these drugs could be enormous. This is likely to only become worse since the combined use of atypical antipsychotics and antidepressants currently being approved and promoted is likely to have a synergistic effect on infant mortality. Since companies monitor this public information for their own as well as competitor's agents, and since similar cases are likely being reported directly to companies, it is almost certain that companies marketing atypical antipsychotics, including Merck/Schering-Plough, are aware of this danger, yet none of these drugs contain any labeled warnings. In fact, it is the exact opposite. Women are warned of the dangers of leaving bipolar disorder untreated during pregnancy and are told antipsychotics pose very little risk to the fetus.

239. Ninety percent of drugs removed from the market are due to toxic metabolites. In fact, thalidomide-induced birth defects are due to a toxic metabolite. One of the reasons thalidomide was not approved and kept off the U.S. market is the lack of drug metabolite/mass balance information of the type that is missing from the Saphris® new drug application. Because of thalidomide, since October 1962 the FDCA has required that "reasonable" attempts be made to generate and provide the type of information that was missing from the Saphris application for a drug to be approved. Reasonable attempts were not made by Merck/Schering-

Plough, in Dr. Kavanagh's expert opinion,[23] and the mass balance study was intentionally designed to prevent the ability to detect, identify, and quantify metabolites. This was documented in Dr. Kavanagh's review of Saphris®. Notwithstanding this, Merck/Schering pushed for Saphris®' approval, and persuaded FDA management to improperly agree that the study was adequate. Consequently, Merck/Schering-Plough obtained approval of Saphris® in violation of the FDCA.

COUNT I
FALSE CLAIMS ACT-MERCK
31 U.S.C. § 3729(a)(1)(A)

240. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

241. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729-3733 against Merck for knowingly causing to be presented false claims to Government Healthcare Programs. From in or about 2009 to the present, Merck has knowingly and willfully caused to be presented false claims as described in this Complaint.

242. By virtue of the acts described above, Merck has knowingly caused physicians to prescribe Saphris® and pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Saphris® knowing that such false claims would be submitted to Government Healthcare Programs for reimbursement.

243. Merck has also violated 31 U.S.C. §3729(a)(1)(A) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement

[23] Dr. Kavanagh received his Ph.D. in the foremost program in the world for drug metabolism, majoring in pharmacokinetics with a minor in drug metabolism and did research in drug metabolism, enzyme kinetics, and transporters, and their correlation to *in vivo* effects for his Ph.D. thesis.

of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Saphris® were paid for in compliance with federal law.

244. The government, unaware of the falsity of the claims made or caused to be made by Merck, paid and continues to pay claims that would not be paid but for Merck's omissions and misrepresentations.

245. By virtue of the false claims caused to be presented by Merck, the United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim presented or caused to be presented.

COUNT II
FALSE CLAIMS ACT-MERCK
31 U.S.C. §§ 3729(a)(1)(B)

246. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

247. Merck has used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for reimbursement under the Government Healthcare Programs, which claims would not have been reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®.

248. From in or about 2009 to the present, Merck's conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(B).

249. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim paid or approved.

WHEREFORE, as to Counts I-II, Relator respectfully requests that this Court enter judgment against the Merck defendant(s), as follows:

(a) That the United States be awarded damages in the amount of three times the damages it sustained because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*. provides;

(b) That statutory civil penalties of $10,000 (adjusted for inflation) be imposed for each and every false claim that the Merck defendants caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre and post judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT III
FALSE CLAIMS ACT-PFIZER
31 U.S.C. § 3729(a)(1)(A)

250. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

251. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729-3733 against Pfizer for knowingly causing to be presented false claims to Government Healthcare Programs. From in or about 2009, through to the present, Pfizer has knowingly and willfully caused to be presented false claims as described in this Complaint.

252. By virtue of the acts described above, Pfizer has knowingly caused physicians to prescribe Geodon® and pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Geodon® knowing that such false claims would be submitted to Government Healthcare Programs for reimbursement.

253. Pfizer has also violated 31 U.S.C. §3729(a)(1)(A) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Geodon® were paid for in compliance with federal law.

254. The government, unaware of the falsity of the claims made or caused to be made by Pfizer, paid and continues to pay claims that would not be paid but for Pfizer's omissions and misrepresentations.

255. By virtue of the false claims caused to be presented by Pfizer, the United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim presented or caused to be presented.

COUNT IV
FALSE CLAIMS ACT-PFIZER
31 U.S.C. §§ 3729(a)(1)(B)

256. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

257. Pfizer has used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for reimbursement under the Government Healthcare Programs, which claims would not have been

reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Geodon®.

258. From in or about 2009 to the present, Pfizer's conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(B).

259. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim paid or approved.

WHEREFORE, as to Counts III-IV, Relator respectfully requests that this Court enter judgment against Pfizer, as follows:

(a) That the United States be awarded damages in the amount of three times the damages it sustained because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*. provides;

(b) That statutory civil penalties of $10,000 (adjusted for inflation) be imposed for each and every false claim that the Pfizer caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre and post judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT V
FALSE CLAIMS ACT-JOHNSON AND JOHNSON
31 U.S.C. § 3729(a)(1)(A)

260. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

261. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729-3733 against Johnson and Johnson for knowingly

causing to be presented false claims to Government Healthcare Programs. From in or about April 2008, through to the present, Johnson and Johnson has knowingly and willfully caused to be presented false claims as described in this Complaint.

262. By virtue of the acts described above, Johnson and Johnson has knowingly caused physicians to prescribe Risperdal® and pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Risperdal® knowing that such false claims would be submitted to Government Healthcare Programs for reimbursement.

263. Johnson and Johnson has also violated 31 U.S.C. §3729(a)(1)(A) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Risperdal® were paid for in compliance with federal law.

264. The government, unaware of the falsity of the claims made or caused to be made by Pfizer, paid and continues to pay claims that would not be paid but for Johnson and Johnson's omissions and misrepresentations.

265. By virtue of the false claims caused to be presented by Johnson and Johnson, the United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim presented or caused to be presented.

COUNT VI
FALSE CLAIMS ACT- JOHNSON AND JOHNSON
31 U.S.C. §§ 3729(a)(1)(B)

266. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

267. Johnson and Johnson has used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for reimbursement under the Government Healthcare Programs, which claims would not have been reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Risperdal®.

268. From in or about April 2008 to the present, Johnson and Johnson's conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(B).

269. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim paid or approved.

WHEREFORE, as to Counts V-VI, Relator respectfully requests that this Court enter judgment against Johnson and Johnson, as follows:

(a) That the United States be awarded damages in the amount of three times the damages it sustained because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*. provides;

(b) That statutory civil penalties of $10,000 (adjusted for inflation) be imposed for each and every false claim that the Johnson and Johnson caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre and post judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT VII
FALSE CLAIMS ACT-LILLY
31 U.S.C. § 3729(a)(1)(A)

181. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

182. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729-3733 against Lilly for knowingly causing to be presented false claims to Government Healthcare Programs. From in or about 2009 through to the present, Lilly has knowingly and willfully caused to be presented false claims as described in this Complaint.

183. By virtue of the acts described above, Lilly has knowingly caused physicians to prescribe Zyprexa® and pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Zyprexa® knowing that such false claims would be submitted to Government Healthcare Programs for reimbursement.

184. Lilly has also violated 31 U.S.C. §3729(a)(1)(A) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Zyprexa® were paid for in compliance with federal law.

185. The government, unaware of the falsity of the claims made or caused to be made by Lilly, paid and continues to pay claims that would not be paid but for Lilly's omissions and misrepresentations.

186. By virtue of the false claims caused to be presented by Lilly, the United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil

penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim presented or caused to be presented.

COUNT VIII
FALSE CLAIMS ACT-LILLY
31 U.S.C. §§ 3729(a)(1)(B)

187. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

188. Lilly has used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for reimbursement under the Government Healthcare Programs, which claims would not have been reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Zyprexa®.

189. From in or about 2009 to the present, Lilly's conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(B).

190. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 (adjusted for inflation) for each false claim paid or approved.

WHEREFORE, as to Counts VII-VIII, Relator respectfully requests that this Court enter judgment against Lilly as follows:

(a) That the United States be awarded damages in the amount of three times the damages it sustained because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*. provides;

(b) That statutory civil penalties of $10,000 (adjusted for inflation) be imposed for each and every false claim that Lilly caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre and post judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT IX
CALIFORNIA FALSE CLAIMS ACT

270. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

271. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

272. Cal. Gov't Code § 12651(a) provides liability for any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;
> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

273. Defendants violated Cal. Gov't Code § 12651(a) and knowingly caused false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in

connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

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

275. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct.

276. Had the State of California known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

277. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

278. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

279. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X
DELAWARE FALSE CLAIMS AND REPORTING ACT

280. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

281. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

6 Del. C. § 1201(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

282. Defendants violated 6 Del. C. § 1201(a) and knowingly caused false claims to be made, used and presented to the State of Delaware by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

284. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct.

285. Had the State of Delaware known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

286. As a result of Defendants' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

287. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

288. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Delaware:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Delaware;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XI
FLORIDA FALSE CLAIMS ACT

289. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

290. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

291. Fla. Stat. § 68.082(2) provides liability for any person who:

> (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;
> (c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

292. Defendants violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

293. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

294. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct.

295. Had the State of Florida known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

296. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

297. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

298. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Florida;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XII
GEORGIA FALSE MEDICAID CLAIMS ACT

299. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

300. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 (2008) *et seq.*

301. O.C.G.A. § 49-4-168.1(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
(3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

302. Defendants violated O.C.G.A. § 49-4-168 *et seq.* by engaging in the conduct described herein.

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

304. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct.

305. Had the State of Georgia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

306. As a result of Defendants' violations of O.C.G.A. § 49-4-168, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

307. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to O.C.G.A. § 49-4-168 on behalf of himself and the State of Georgia.

308. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Georgia:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Georgia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to O.C.G.A. § 49-4-168 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIII
HAWAII FALSE CLAIMS ACT

309. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

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

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

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
> (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

312. Defendants violated Haw. Rev. Stat. §661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

313. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

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

315. Had the State of Hawaii known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

316. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

317. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

318. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV
ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

319. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

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

321. 740 ILCS 175/3(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

322. Defendants violated 740 ILCS 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

323. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

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

condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct.

325. Had the State of Illinois known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

326. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

327. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

328. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Illinois;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

329. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

330. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 *et seq*. provides:

> Sec. 2.(b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6)

331. Defendants violated Indiana Code 5-11-5.5 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in

connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

332. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

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

334. Had the State of Indiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

335. As a result of Defendants' violations of Indiana Code 5-11-5.5 *et seq.*, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

336. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Indiana Code 5-11-5.5 *et seq.* on behalf of himself and the State of Indiana.

337. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 for each false claim which Defendants caused to be presented to the State of Indiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVI
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

338. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

339. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

340. La. Rev. Stat. Ann. § 438.3 provides:

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

341. Defendants violated La. Rev. Stat. Ann. §438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic

violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

344. Had the State of Louisiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

345. As a result of Defendants' violations of La. Rev. Stat. Ann. § 438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

346. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of himself and the State of Louisiana.

347. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVII
MASSACHUSETTS FALSE CLAIMS ACT

348. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

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

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

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth; or
(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

> (4) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

351. Defendants violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

352. The Commonwealth of Massachusetts, by and through the Massachusetts Medic-aid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

353. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' conduct.

354. Had the Commonwealth of Massachusetts known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

355. As a result of Defendants' violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

356. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2) on behalf of themselves and the Commonwealth of Massachusetts.

357. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12, §5F and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII
MICHIGAN MEDICAID FALSE CLAIMS ACT

358. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

359. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. MI ST Ch. 400.603 *et seq.*

400.603 provides liability in pertinent part as follows:

> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits;
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit...

360. Defendants violated, MI ST Ch. 400.603 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

363. Had the State of Michigan known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

364. As a result of Defendants' violations of MI ST Ch. 400.603 *et seq.*, the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

365. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to MI ST Ch. 400.603 *et seq.* on behalf of himself and the State of Michigan.

366. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Michigan:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Michigan;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIX
MINNESOTA FALSE CLAIMS ACT

367. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

368. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*

Section 15C.01 provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim.

369. Defendants violated, Minn. Stat. § 15C.01 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Minnesota by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct.

372. Had the State of Minnesota known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

373. As a result of Defendants' violations of Minn. Stat. § 15C.01 *et seq.*, the State of Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of interest.

374. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Minn. Stat. § 15C.01 *et seq.* on behalf of himself and the State of Minnesota.

375. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Minnesota:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Minnesota ;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Minn. Stat. § 15C.13 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX
MONTANA FALSE CLAIMS ACT

376. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

377. This is a claim for treble damages and penalties under the Montana False Claims Act, M.C.A.§17-8-401 *et seq*.

378. Section 17-8-403 of the Montana False Claims Act provides liability for any person who:

(a) knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity;
(c) conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the governmental entity.

379. Defendants violated, M.C.A § 17-8-403 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Montana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

380. Each prescription that was written as a result of Defendants' illegal conduct represents a false or fraudulent record or statement. And, each claim for reimbursement written for Saphris®, Geodon®, Risperdal® and Zyprexa®, submitted to Montana represents a false or fraudulent claim for payment.

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

382. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendants' conduct.

383. Had the State of Montana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa® it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

384. As a result of Defendants' violations of M.C.A.§ 17-8-401 *et seq.*, the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

385. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to M.C.A.§ 17-8-406 *et seq.* on behalf of himself and the State of Montana.

386. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Montana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Montana:

(1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Montana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to M.C.A. § 17-8-410 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXI
NEVADA FALSE CLAIMS ACT

387. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

388. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et. seq.*

389. N.R.S. § 357.040(1) provides liability for any person who:

> (a) knowingly presents or causes to be presented a false claim for payment or approval;

> (b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
> (c) conspires to defraud by obtaining allowance or payment of a false claim;
> (h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

390. Defendants violated N.R.S. § 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

391. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

392. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct.

393. Had the State of Nevada known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

394. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

395. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

396. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action..

To Relator:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXII
NEW JERSEY FALSE CLAIMS ACT

397. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

398. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §

2A:32C-1 (2008) *et seq.*

399. N.J. Stat. § 2A:32C-1 provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee, officer or agent of the State or to any contractor, grantee, or other recipient of State funds a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

400. Defendants violated N.J. Stat. § 2A:32C-1 and knowingly caused false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

401. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

402. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct.

403. Had the State of New Jersey known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

404. As a result of Defendants' violations of N.J. Stat. § 2A:32C-1, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

405. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. § 2A:32C-1 *et seq.* on behalf of himself and the State of New Jersey.

406. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII
NEW MEXICO MEDICAID FALSE CLAIMS ACT

407. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

408. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann§§ 27-14-1 *et seq.*, which in pertinent part provides liability to any person who:

> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee, or other recipient of state funds a false or fraudulent claim for payment or approval;
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
> (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim.

409. Defendants violated, N.M. Stat. Ann§§ 27-14-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

410. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

411. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct.

412. Had the State of New Mexico known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of

Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

413. As a result of Defendants' violations of N.M. Stat. Ann§§ 27-14-1 *et seq.*, the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

414. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann§§ 27-14-1 *et seq.* on behalf of himself and the State of New Mexico.

415. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Mexico:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann §§ 27-14-1 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIV
NEW YORK FALSE CLAIMS ACT

416. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

417. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N.Y. Laws 58, Section 39, Article XIII (McKinney's State Finance Laws §187 *et seq*.). The New York False Claims Act provides liability for any person who:

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;
(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

418. Defendants violated the New York False Claims Act and knowingly caused false claims to be made, used and presented to the State of New York by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

419. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

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

condition of payment of claims submitted to the State of New York in connection with Defendants' conduct.

421. Had the State of New York known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

422. As a result of Defendants' violations of 2007 N.Y. Laws 58, Section 39, Article XIII, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

423. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, on behalf of himself and the State of New York.

424. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New York:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendants caused to be presented to the State of New York;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII (McKinney's State Finance Laws §190), and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXV
NORTH CAROLINA FALSE CLAIMS ACT

425. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

426. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S § 1-605 *et seq.*

Section 1-607 of this Act provides liability for any person who:

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
(3) Conspires to commit a violation of subdivision (1), (2), ...of this section.

427. Defendants violated, N.C.G.S § 1-605 *et seq.* and knowingly caused false claims to be made, used and presented to the State of North Carolina by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

428. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submit-ted by healthcare providers and third party payers in connection therewith.

429. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct.

430. Had the State of North Carolina known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by health-care providers and third party payers in connection with that conduct.

431. As a result of Defendants' violations of N.C.G.S § 1-605 *et seq.*, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

432. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C.G.S § 1-608(b) on behalf of himself and the State of North Carolina.

433. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of North Carolina:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of North Carolina;
(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.C.G.S § 1-610 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVI
OKLAHOMA MEDICAID FALSE CLAIMS ACT

434. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

435. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act 63 Okl. St. § 5053 (2008) *et seq.*

436. 63 Okl. St. § 5053.1 (2)(B) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

437. Defendants violated 63 Okl. St. § 5053.1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

439. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct.

440. Had the State of Oklahoma known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

441. As a result of Defendants' violations of 63 Okl. St. § 5053.1 *et seq.*, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

442. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. § 5053.1 *et seq.* on behalf of himself and the State of Oklahoma.

443. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Oklahoma:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 63 Okl. St. § 5053.1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVII
RHODE ISLAND STATE FALSE CLAIMS ACT

444. Plaintiffs repeat and reallege each allegation contained in paragraphs 1-239 above as if fully set forth herein.

445. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act R.I. Gen. Laws § 9-1.1-1 (2008) *et seq.*

446. R.I. Gen. Laws § 9-1.1-1 provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

447. Defendants furthermore violated R.I. Gen. Laws § 9-1.1-1 and knowingly caused false claims to be made, used and presented to the State of Rhode Island by their deliberate and

systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

448. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

449. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' conduct.

450. Had the State of Rhode Island known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

451. As a result of Defendants' violations of R.I. Gen. Laws § 9-1.1-1, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

452. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-1 *et seq.* on behalf of himself and the State of Rhode Island.

453. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Rhode Island:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII
TENNESSEE FALSE CLAIMS ACT

454. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

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

§ 71-5-182(a)(1) provides liability for any person who:

> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

456. Defendants violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

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

459. Had the State of Tennessee known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

460. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

461. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

462. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIX
TEXAS MEDICAID FRAUD PREVENTION LAW

463. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

464. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

465. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who:

> (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
>
> (a) on an application for a contract, benefit, or payment under the Medicaid program; or
>
> (b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program;
>
> (2) knowingly or intentionally concealing or failing to disclose an event:
>
> (a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of
>
> (i) the person, or
>
> (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
>
> (b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
>
> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> (b) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

466. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

467. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

468. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct.

469. Had the State of Texas known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

470. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

471. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

472. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

473. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $15,000 pursuant to V.T.C.A. Hum. Res. Code § 36.052(a)(3) for each false claim which Defendants cause to be presented to the State of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXX
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

474. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

475. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Tax Payers Act. Sec. 8.01-216.3a which provides liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth; or
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof,

> subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

476. Defendants furthermore violated Virginia Fraud Against Tax Payers Act §8.01-216.3a and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

477. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submit-ted by healthcare providers and third party payers in connection therewith.

478. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct.

479. Had the Commonwealth of Virginia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by health-care providers and third party payers in connection with that conduct.

480. As a result of Defendant's violations of Virginia Fraud Against Tax Payers Act §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

481. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Virginia Fraud Against Tax Payers Act §8.01-216.3 on behalf of themselves and the Commonwealth of Virginia.

482. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the Commonwealth of Virginia:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to VA Code ANN § 32.1-315 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXXI
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW

483. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

484. This is a *qui tam* action brought by Relator on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical

Assistance Law, Wis. Stat. § 20.931 *et seq.*

485. Wis. Stat. § 20.931(2) provides liability for any person who:

> (1) conspires to defraud this State by obtaining a false allowance or payment of claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;
> (2) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance Program.

486. Defendants violated Wis. Stat. § 20.931 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Wisconsin by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

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

488. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendants' conduct.

489. Had the State of Wisconsin known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa® it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

490. As a result of Defendants' violations of Wis. Stat. § 20.931 *et seq.*, the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

491. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. § 20.931 *et seq.* on behalf of himself and the State of Wisconsin.

492. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Wisconsin:

(1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXXII
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

493. Relator realleges and incorporates by reference paragraphs 1 through 239 as though fully set forth herein.

494. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

495. D.C. Code § 2-308.14(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
(3) conspires to defraud the District by getting a false claim allowed or paid by the District;
(4) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

496. Defendants violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

497. The District of Columbia, by and through the District of Columbia Medicaid program and other state healthcare programs, and unaware of Defendants' illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

498. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Defendants' illegal conduct.

499. Had the District of Columbia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Saphris®, Geodon®, Risperdal® and Zyprexa®, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

500. As a result of Defendants' violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

501. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

502. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;
(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States and on his own behalf, demands judgment against Defendants, as follows:

A. That Defendants cease and desist from violating 31 U.S.C.§3729 et. seq., and the equivalent provisions of the state statutes set forth above.

B. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each false claim, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action.

C. That this Court enter judgment against the Defendants for the maximum amount of actual damages and civil penalties permitted under the false claims statutes of the respective States discussed in this Complaint.

D. That Relator be awarded all costs incurred, including his attorneys' fees.

E. That, in the event the United States Government intervenes in this action, Relator be awarded the maximum allowable percentage of any proceeds of the claim, and that, in the event the United States Government does not intervene in this action, Relator be awarded 30% of any proceeds.

F. That the United States and Relator receive all relief, both in law and in equity, to which they are entitled.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of Federal Rules of Civil Procedure, Plaintiffs and Relator hereby demand a trial by jury.

Dated: December 7, 2012

Respectfully submitted,

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Attorneys for Relator, Ronald E. Kavanagh

Exhibit 1

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MERCK & CO., INC.

I. PREAMBLE

Merck & Co., Inc. (Merck) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements).

Prior to the Effective Date, Merck voluntarily established a comprehensive Compliance Program. The Compliance Program includes: a Global Support/U.S. Compliance Officer (who is the Compliance Officer for Global Pharmaceuticals, the Merck Vaccines and Infectious Diseases Division (MVID), and the Global Market & Franchise Business Support Organization (GMFBS)) (referred to hereafter as the "Compliance Officer"), a Compliance Committee, and the Global Support/U.S. Business Practices and Compliance Organization that works in conjunction with Merck's Chief Ethics and Compliance Officer (Ethics Officer). The Compliance Program also includes: a code of conduct; Merck's Ethical Operating Standards; written Policies and Guidance Documents which address ethics and integrity, compliance with Federal laws and regulations, and appropriate business practices; mandatory training concerning Merck's Ethical Operating Standards and Policies and Guidance Documents; internal review procedures; a multi-faceted Disclosure Program; and screening measures for Ineligible Persons. As represented by Merck, the existing Compliance Program is designed to meet Merck's goals of promoting ethical standards in all aspects of its business practices and compliance with all policies and guidance.

Contemporaneously with this CIA, Merck is entering into two Settlement Agreements (Settlement Agreements) with the United States. Merck will also enter into settlement agreements with various states and Merck's agreement to this CIA is a condition precedent to those settlement agreements.

Merck shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Merck may modify its Compliance Program as appropriate, but, at a minimum, Merck shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Merck under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Merck's final Annual Report; or (2) any additional materials submitted by Merck pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

   a. all owners of Merck who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);

   b. all officers of Merck;

   c. all directors of Merck;

   d. the Ethics Officer and the Compliance Officer;

   e. employees of Merck's Office of General Counsel who are engaged in, or have responsibilities that directly support, the Covered Functions as defined below in Section II.C.5;

f. employees of Merck's Corporate Finance Organization who are engaged in, or have responsibilities that directly support, the Covered Functions as defined below in Section II.C.5;

g. all employees of U.S. Pharmaceuticals (U.S. Pharma);

h. U.S.-based personnel who are assigned to MVID, Global Pharmaceuticals, GMFBS, or any other Merck divisions and who are engaged in, or have responsibilities that directly support, the Covered Functions as defined below in Section II.C.5; and

i. all contractors, subcontractors, agents, and other persons who perform Government Pricing and Contracting Functions (as defined below in Section II.C.3) or who perform Promotional and Product Services Related Functions (as defined below in Section II.C.5) on behalf of Merck.

If, during the term of this CIA, there are changes in the organizational structure of Merck, all employees of U.S. Pharma, MVID, Global Pharmaceuticals, GMFBS and/or all other Merck components who are engaged in, or have responsibilities that directly support, Covered Functions (as defined below in Section II.C.5) shall be considered "Covered Persons."

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons described above in Sections II.C.1 (a)-(i) who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes those Covered Persons whose job responsibilities relate to Government Pricing and Contracting Functions (as defined below in Section II.C.3) or to Promotional and Product Services Related Functions (as defined below in Section II.C.5).

3. The term "Government Pricing and Contracting Functions" refers to the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. §

1396r-8), the Medicare Program (42 U.S.C. §§ 1395-1395hhh), and other government programs (including the 340B Drug Pricing Program, codified at 42 U.S.C. § 256b (the 340B Program)). This includes individuals whose job responsibilities include the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, the 340B Program ceiling price, Average Wholesale Price (AWP) (if applicable), and all other information calculated and reported by Merck and used in connection with Federal health care programs.

4. The term "Government Reimbursed Products" refers to those Merck products (including vaccines) that are reimbursed by Federal health care programs.

5. The term "Promotional and Product Services Related Functions" refers to the promotion, marketing, sales, or provision of information about, or services relating to, Government Reimbursed Products in or for the United States market.

   "Government Pricing and Contracting Functions" and "Promotional and Product Services Related Functions" shall be collectively referred to herein as the "Covered Functions."

6. The term "Third Party Personnel" shall mean employees of the entities with whom Merck has or may in the future enter into agreements to co-promote a Merck product or engage in joint promotional activities relating to a Merck product. Merck represents that: 1) the Third Party Personnel are employed by other independent entities; 2) Merck does not control Third Party Personnel; and 3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Merck agrees to promote compliance by Third Party Personnel with Federal health care program requirements by complying with the provisions set forth below in Sections III.B.3, V.A.2, and V.B.4 related to Third Party Personnel. Provided that Merck complies with the requirements of Sections III.B.3, V.A.2, and V.B.4, Merck shall not be required to fulfill the remaining CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

7. The term "Acknowledge" as used in this CIA means a written verification that the signatory agrees with the statements set forth in the verification.

III. CORPORATE INTEGRITY OBLIGATIONS

Merck shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Generally.* Prior to the Effective Date, Merck established the Global Support/U.S. Business Practices & Compliance Organization (BP&C). Among other things, BP&C has responsibility for the design, development, and implementation of compliance practices and processes guiding sales and marketing activities for Global Pharmaceuticals, U.S. Pharma, MVID and GMFBS. BP&C is headed by the Compliance Officer. The President of Global Pharmaceuticals (President) and the Compliance Officer co-chair the Compliance Committee (the "Compliance Committee"). The members of the Compliance Committee include the Compliance Officer, the president of MVID, the head of GMFBS, and the head of U.S. Pharma. The Ethics Officer is responsible for Merck's corporate-wide Office of Ethics and Compliance.

2. *Compliance Officer.* Prior to the Effective Date, Merck appointed an individual to serve as its Compliance Officer. Merck maintains and shall continue to maintain a Compliance Officer during the term of the CIA. The Compliance Officer is responsible and shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer reports to the President. The Compliance Officer is and shall continue to be a member of senior management of Global Pharmaceuticals. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Merck. The Compliance Officer is authorized and shall continue to be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer is responsible and shall continue to be responsible for monitoring the day-to-day compliance activities engaged in by Global Pharmaceuticals, U.S. Pharma, MVID, and GMFBS, as well as for any reporting obligations created under this CIA.

Merck shall report to OIG, in writing, any changes in the identity or position descriptions of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Compliance Committee.* Prior to the Effective Date, Merck established the Compliance Committee, which, in conjunction with the Compliance Officer, has primary responsibility for promoting compliance within Global Pharmaceuticals, U.S. Pharma, MVID, and GMFBS. Merck shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, continue to include the Compliance Officer, the President, the Ethics Officer, and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant Merck business units, finance, human resources, and the Office of General Counsel). The Compliance Officer (along with the President) chairs and shall continue to chair the Compliance Committee, and the Committee supports and shall continue to support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Merck shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Generally.* Prior to the Effective Date, Merck created, disseminated, and implemented written standards regarding ethics and integrity, compliance with Federal laws and regulations, and appropriate business practices related to both the Federal health care programs and the sales and marketing activities of Global Pharmaceuticals, U.S. Pharma, MVID, and GMFBS.

2. *Code of Conduct.* Prior to the Effective Date, Merck established both a general corporate Code of Conduct and a set of Ethical Operating Standards. Merck's Ethical Operating Standards provide guidance relating to the Covered Functions, including the promotion, marketing, and sale of Merck's products in the United States. Merck has made (or, within 90 days after the Effective Date, shall make) the Ethical

Operating Standards available to all Covered Persons. Merck makes, and shall continue to make, adherence to these Ethical Operating Standards an element in evaluating the performance of all employees who are Covered Persons.

The Ethical Operating Standards include, and shall continue to include:

a. Merck's commitment to full compliance with all Federal health care program requirements, including its commitment to comply with all requirements relating to Government Pricing and Contracting Functions and to promote, sell, and market its products in accordance with Federal health care program requirements;

b. Merck's requirement that all of its Covered Persons shall be expected to comply with all applicable legal requirements, with all Federal health care program requirements, and with Merck's own Policies and Guidance Documents (defined below in Section III.B.4), including but not limited to, the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);

c. Merck's requirement that Covered Persons are responsible for adhering to the Ethical Operating Standards and are expected to report suspected violations of any Federal health care program requirements or of Merck's own Ethical Operating Standards;

d. the personal obligations of each Covered Person to comply with Federal health care program requirements and the Ethical Operating Standards;

e. the possible consequences to both Merck and Covered Persons of failure to comply with Federal health care program requirements and/or with Merck's own Ethical Operating Standards, or the failure to report such noncompliance; and

f. the right of all individuals to use the Disclosure Program described in Section III.E, and Merck's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 90 days after the Effective Date, each Covered Person shall Acknowledge in writing or in electronic form (if applicable), that he or she has received, read, understood, and shall abide by the Ethical Operating Standards. New Covered Persons shall receive the Ethical Operating Standards and shall complete the required Acknowledgement within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Merck represents that it reviews its Ethical Operating Standards annually to determine if revisions are appropriate and makes any necessary revisions based on such review. Merck shall continue such reviews and revisions throughout the term of the CIA. Within 30 days after the effective date of any revisions, the relevant portions of the revised Ethical Operating Standards shall be made available on Merck's intranet site or through another means to Covered Persons. Each Covered Person shall Acknowledge, in writing or electronically, within 30 days after the revised Ethical Operating Standards are made available to him or her, and that he or she has received, read, understood, and shall abide by the revised Ethical Operating Standards.

3. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Merck shall send a letter to each entity employing Third Party Personnel. The letter shall describe Merck's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of Merck's Compliance Program. Merck shall attach a copy of its Ethical Operating Standards to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Merck's Ethical Operating Standards and a description of Merck's Compliance Program available to its employees who meet the definition of Third Party Personnel as set forth in Section II.C.6; or (b) represent to Merck that it has and enforces a substantially comparable set of Ethical Operating Standards (or code of conduct) and Compliance Program for its employees who meet the definition of Third Party Personnel as set forth in Section II.C.6.

4. *Policies and Procedures.* Prior to the Effective Date, Merck established and implemented Field Policy Letters and Headquarters Guidance Documents related to Promotional and Product Services Related Functions. Prior to the Effective Date, Merck also established and implemented written Government Price Reporting Policies regarding Government Pricing and Contracting Functions (Customer Contract Management Policies). These Field Policy Letters, Headquarters Guidance Documents, and Customer

Contract Management Policies, which are collectively known as "Policies and Guidance Documents," address and shall continue to address:

a. selling, marketing, and promoting Merck's products in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute and the False Claims Act;

b. consultant arrangements entered into with health care professionals (including, but not limited to, speaker programs, speaker meetings, advisory board meetings, training programs, colloquiums, roundtables, and forums, as applicable) and all events relating to these arrangements. These policies shall be designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements;

c. sponsorship or funding of grants (including educational grants). These policies shall be designed to ensure that Merck's funding and/or sponsorship complies with all applicable Federal health care program requirements;

d. sponsorship or funding of research or related activities. These policies shall be designed to ensure that Merck's funding and/or sponsorship complies with all applicable Federal health care program requirements;

e. policies and procedures relating to compensation (including salaries and bonuses) for Covered Persons that are designed to ensure that financial incentives do not exist for the improper promotion, sales, and marketing of Merck's products;

f. Government Pricing and Contracting Functions; and

g. policies and procedures relating to disciplinary action for violations of Merck's Policies and Guidance Documents.

Prior to the Effective Date, Merck made the relevant Policies and Guidance Documents available to all Covered Persons who are employees and whose job functions relate to those Policies and Guidance Documents. To the extent not already accomplished, within 90 days after the Effective Date Merck shall make the Policies and Guidance Documents available to all Covered Persons whose job functions relate to those Policies and Guidance Documents. Appropriate and knowledgeable staff is, and shall continue to be, available to explain the Policies and Guidance documents.

At least annually (and more frequently, if appropriate), Merck assesses and revises as necessary, the Policies and Guidance Documents. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Guidance Documents are made available to all individuals whose job functions relate to those Policies and Guidance Documents. Merck shall continue the practices described in this paragraph during the term of this CIA.

C. Training and Education.

1. *Generally*. Prior to the Effective Date, Merck provided two levels of training to Covered Persons who are employees: Awareness Training and Knowledge Training. Merck shall provide or continue to provide Awareness Training and Knowledge Training to all Covered Persons throughout the term of this CIA as set forth in Sections III.C.2-3 below.

2. *Awareness Training*. Merck shall provide annual training to Covered Persons on the Ethical Operating Standards through an in-person or computer-based training program. Prior to the Effective Date, this training (known as "Awareness Training") covered Merck's Compliance Program and the content of the Ethical Operating Standards described in Section III.B.2. Following the Effective Date, the Awareness Training shall cover:

a. Merck's Compliance Program (including the Ethical Operating Standards); and
b. Merck's obligations under this CIA.

Within 90 days after the Effective Date, Merck shall provide one hour of Awareness Training to, and obtain an Acknowledgement (as set forth in Section III.C.4) from, each Covered Person. After receiving the initial Awareness Training described

above for the first Reporting Period, each Covered Person shall receive at least one hour of Awareness Training in each subsequent Reporting Period.

To the extent that Merck provided Awareness Training to Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.2.a above, the OIG shall credit that training for purposes of satisfying Merck's Awareness Training obligations of Section III.C.2 for the first Reporting Period. Merck may satisfy its remaining Awareness Training obligations for the Covered Persons who received the training described in the preceding sentence by notifying them within 90 days after the Effective Date in writing or in electronic format of the fact that Merck entered a CIA and providing an explanation of Merck's requirements and obligations under the CIA.

Individuals who become Covered Persons following the Effective Date (*i.e.*, new Covered Persons) shall receive the Awareness Training and provide an Acknowledgement (as set forth in Section III.C.4) within 45 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

3. *Knowledge Training*. Merck shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training is known as "Knowledge Training."

For those Relevant Covered Persons engaged in Promotional and Product Services Related Functions, to the extent not covered by Awareness Training, Knowledge Training includes, and shall continue to include, a discussion of:

a. all applicable Federal health care program requirements relating to the promotion, sales, and marketing of Government Reimbursed Products (as defined above in Section II.C.4);

b. all Merck policies, procedures, and other requirements applicable to promotion, sales, and marketing of Government Reimbursed Products;

c. the personal obligation of each individual involved in the promotion, sales, or marketing of Government Reimbursed Products to comply with applicable legal requirements;

d. the legal sanctions for violations of the Federal health care program requirements; and

e. examples of proper and improper practices related to the promotion, sales, and marketing of Government Reimbursed Products.

For those Relevant Covered Persons engaged in Government Pricing and Contracting Functions, to the extent not covered by Awareness Training, Knowledge Training includes, and shall continue to include, a discussion of:

a. Merck' systems and processes relating to Government Pricing and Contracting Functions;

b. all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions;

c. the personal obligation of each individual involved in Government Pricing and Contracting Functions to ensure that all reported pricing and other information is accurate;

d. the legal sanctions for violations of Federal health care program requirements; and

e. examples of proper and improper practices related to Government Pricing and Contracting Functions.

Within 90 days after the Effective Date, Merck shall provide two hours of Knowledge Training to, and obtain an Acknowledgement (described in Section III.C.4) from, each Relevant Covered Person. After receiving the initial Knowledge Training described above for the first Reporting Period, each Relevant Covered Person shall receive at least two hours of Knowledge Training in each subsequent Reporting Period.

To the extent that Merck provided Knowledge Training to Relevant Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.3 above, the OIG shall credit that training for purposes of satisfying Merck's Knowledge Training obligations of this Section III.C.3 for the first Reporting Period.

Individuals who become Relevant Covered Persons following the Effective Date (*i.e.*, new Relevant Covered Persons) shall receive the Knowledge Training and provide an Acknowledgement within 45 days after becoming a Relevant Covered Person or within 90 days after the Effective Date, whichever is later. A Relevant Covered Person who has completed the Knowledge Training shall review the work of a new Relevant Covered Person, to the extent that the work relates to (as applicable) Government Pricing and Contracting Functions or Promotional and Product Services Functions, until such time as the new Relevant Covered Person completes his or her Knowledge Training.

4. *Acknowledgement.* Each Covered Person who is required to complete Awareness Training and each Relevant Covered Person who is required to also complete Knowledge Training shall acknowledge, in writing or in electronic form, if applicable, that he or she has received such training and the date such training was received. The Compliance Officer (or designee) shall retain these Acknowledgements, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons responsible for providing the Awareness Training and the Knowledge Training shall be knowledgeable about the subject area of the training.

6. *Update of Training.* Merck represents that it reviews its training annually, and, where appropriate, updates the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information. Merck shall continue the reviews and updates described in the preceding sentence during the term of the CIA.

7. *Computer-based Training.* Merck may provide the training required under this CIA through appropriate computer-based training approaches. If Merck chooses to provide computer-based training, it makes and shall continue to make available appropriately qualified and knowledgeable trainers to answer questions or provide additional information to the individuals receiving such training. If Merck chooses to provide computer-based Awareness or Knowledge Training, all applicable requirements to provide a number of "hours" of training as set forth in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description of Merck's Internal Review Procedures.* Merck represents that prior to the Effective Date, Merck designed and implemented oversight and reporting mechanisms by which it monitors certain activities of Covered Persons including those involving Government Pricing and Contracting Functions and those involving Promotional and Product Services Related Functions. Merck shall continue oversight and reporting mechanisms throughout the term of this CIA.

2. *Description of Reviews Required by CIA.* During the term of the CIA, Merck and the Independent Review Organization (IRO) (as defined below) shall perform two general types of reviews designed to assess and evaluate Merck's Government Pricing and Contracting Functions (Medicaid Drug Rebate Review) and its Promotional and Product Services Related Functions (Promotional and Product Services Review). As more fully explained below and in Appendix A, which is incorporated by reference, the Medicaid Drug Rebate Review shall consist of reviews of samples of transactions relevant to the Average Manufacturer Prices and Best Prices reported to CMS for purposes of the Medicaid Drug Rebate Program. As more fully explained below and in Appendix B, which is incorporated by reference, the Promotional and Product Services Review shall consist of two components – a systems review (the Promotional and Product Services Systems Review) and a transactions review (Promotional and Product Services Transactions Review). The IRO shall conduct all parts of the Promotional and Product Services Systems Review. Merck may conduct the Medicaid Drug Rebate Review and/or the Promotional and Product Services Transactions Review using its internal audit resource with prior annual approval of the OIG. If Merck elects to conduct the aforementioned reviews using internal audit resources, the IRO shall conduct Verification Reviews of Merck's Reviews as set forth more fully in Appendices A and B. If Merck does not elect to conduct the Medicaid Drug Rebate Review and the Promotional and Product Services Transactions Review using internal audit resources, the IRO shall conduct all components of the reviews. The reviews conducted by Merck and the IRO shall be referred to generally as the "Reviews."

3. *General Description of Independent Review Organization.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Merck shall engage an entity (or entities), such as an accounting, auditing, or consulting firm as an IRO to perform the Reviews described in Section III.D.2. The applicable

requirements relating to the IRO are outlined in Appendix C to this CIA, which is incorporated by reference.

Each IRO engaged by Merck shall have expertise in the applicable requirements of the Medicaid Drug Rebate Program, the Medicare and Medicaid programs generally (as applicable), and other applicable Federal health care program requirements. Each IRO shall assess, along with Merck, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

b. *Frequency of Reviews.* The Medicaid Drug Rebate Review and the Promotional and Product Services Transactions Review shall each be performed annually. The Promotional and Product Services Systems Reviews shall be performed for at least the first and fourth Reporting Periods.

If there are no material changes in Merck's systems, processes, policies, and practices relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. As set forth in Appendix B, if Merck materially changes its systems, processes, policies, and practices relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods.

c. *Retention of Records.* The IRO and Merck shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those generated by Merck in connection with any internal audits and those exchanged between the IRO and Merck) related to the Reviews.

4. *IRO and Internal Audit Review Reports.* Merck (if applicable) and the IRO shall prepare a report (Report) for each Medicaid Drug Rebate Review and each Promotional and Product Services Review performed. Information to be included in each

Report is described in Appendices A and B. As set forth in Section V below, these Reports shall be included in each Annual Report.

5. *Validation Review.* In the event OIG has reason to believe that: (a) any Review fails to conform to the requirements of this CIA; or (b) the IRO's or Merck's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable Review complied with the requirements of the CIA and/or the findings or Review results are accurate (Validation Review). Merck shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Merck's final Annual Report shall be initiated no later than one year after Merck's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Merck of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Merck may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the applicable Review; and/or (c) propose alternatives to the proposed Validation Review. Merck agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Merck prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence and Objectivity Certification.* The IRO shall include in its report(s) a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review, and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Effective Date, Merck established a multi-faceted Disclosure Program that enables individuals to raise concerns related to any potential unethical or illegal behavior associated with Federal health care programs or Merck's policies, procedures, or practices confidentially to the Office of Ethics. The Disclosure Program includes Merck's AdviceLine and Ombudsman Program, mechanisms that individuals can access

and for which appropriate confidentiality is maintained. Merck's AdviceLine is a toll-free telephone line staffed by a third-party that is available 24 hours a day, seven days a week. Merck's Ombudsman Program is staffed by individuals in the Office of Ethics. Merck shall continue this Disclosure Program during the term of this CIA. Merck publicizes, and shall continue to publicize, the existence of the Disclosure Program in the Code of Conduct, the Ethical Operating Standards, through training sessions, and by posting information in prominent common areas of Merck's headquarter facilities, on Merck's intranet sites, and on Merck's external website.

The Disclosure Program emphasizes confidentiality and a nonretribution, nonretaliation policy. Merck makes and shall continue to make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Merck conducts and shall continue to conduct an internal review of the allegations set forth in the disclosure. Merck shall ensure that proper follow-up is conducted. Disclosures made through the AdviceLine and the Ombudsman Program are investigated, as appropriate, by a designee from the Office of Ethics, who then determines the appropriate resolution in coordination with the appropriate parties, including the Compliance Officer or designee.

Merck maintains, and shall continue to maintain, a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been

excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" include:

i. prospective and current owners of Merck (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);

ii. prospective and current officers and directors of Merck;

iii. all prospective and current U.S.-based employees of Merck; and

iv. all prospective and current U.S.-based contractors and agents of Merck who are Covered Persons.

2. *Screening Requirements.* Merck shall ensure that all Screened Persons are not Ineligible Persons, by implementing (as applicable) and maintaining the following screening requirements.

a. Merck screens, and shall continue to screen, all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, Merck shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. Merck shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Merck represents that it has a policy in place that requires all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person, and Merck shall maintain such policy during the term of the CIA.

Nothing in this Section affects the responsibility of (or liability for) Merck to refrain from billing (if applicable) Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Merck understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Merck may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Merck meets the requirements of Section III.F.

3. *Removal Requirement.* If Merck has actual notice that a Screened Person has become an Ineligible Person, Merck shall remove such Screened Person from responsibility for, or involvement with, Merck's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Merck has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Merck shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at corporate headquarters, Merck shall notify OIG, in writing, of any ongoing investigation or legal proceeding

known to Merck conducted or brought by a governmental entity or its agents involving an allegation that Merck has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Merck shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by Merck.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events.* If Merck determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Merck shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

ii. a description of actions taken by Merck to correct the Reportable Event; and

iii. any further actions Merck plans to take to address the Reportable Event and prevent it from recurring.

iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

2. Merck shall not be required to report any Reportable Event that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents previously disclosed under Section III.G above.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Merck changes locations or sells, closes, purchases, or establishes a new business unit or location related to Government Pricing and Contracting Functions or to Promotional and Product Services Functions, Merck shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider or supplier number, and the name and address of any corresponding contractor that issued the number. Each new business unit or location meeting criteria set forth in this Section IV shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Certification. Within 120 days after the Effective Date, Merck shall submit a written certification to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Certification). The Implementation Certification shall, at a minimum, include:

1. any changes in the composition of the Compliance Committee since the time that committee members were identified for the OIG, or any actions or change that would affect the Compliance Committee's ability to perform the duties necessary to satisfy the obligations set forth in Section III.A;

2. with regard to the entities employing Third Party Personnel (a) a copy of the letter (including all attachments) required by Section III.B that was and shall continue to be sent to each entity employing the Third Party Personnel; (b) a list and description of all existing co-promotion or other agreements between Merck and the entities employing Third Party Personnel; and (c) a description of the entities' response to Merck's letter;

3. a copy of the Ethical Operating Standards required by Section III.B;

4. an index of the Policies and Guidance Documents required by Section III.B. (Copies of these Policies and Guidance Documents shall be available to the OIG upon request.);

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the format used for the training (*e.g.,* live presentation, computer-based training, *etc.),* the length of sessions, and a schedule of live training sessions;

b. the number of individuals required to participate in training and complete the Acknowledgements required by Section III.C.4, the percentage of individuals who completed the training and Acknowledgements and an explanation for any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Merck and the IRO; and (d) the proposed start and completion dates of the IRO Reviews;

7. a certification from the IRO regarding its professional independence and objectivity with respect to Merck;

8. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;

9. a list of all of Merck's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Merck currently submits claims (if applicable);

10. a description of Merck's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

11. the certifications required by Section V.C.

B. Annual Reports. Merck shall submit to OIG annually a report with respect to the status of, and findings regarding, Merck's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. the number of individuals required to review Merck's Ethical Operating Standards and complete the Acknowledgement required by Section III.B.2, the percentage of individuals who have completed such Acknowledgement, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request)

3. a summary of any significant changes or amendments to the Ethical Operating Standards and/or Policies and Guidance Documents required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and an index of any compliance-related Policies and Guidance Documents not previously identified in the Implementation Certification (if any). (Copies of these Policies and Guidance Documents shall be available to OIG upon request.);

4. with regard to the entities employing Third Party Personnel (a) a copy of the letter (including all attachments) required by Section III.B that was and shall continue to be sent to each entity employing the Third Party Personnel; (b) a list and description of all existing co-promotion or other agreements between Merck and the entities employing Third Party Personnel; and (c) a description of the entities' response to Merck's letter;

5. to the extent not provided in the Implementation Certification, the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the format used for the training (*e.g.*, live presentation, computer-based training, *etc.)*, the length of sessions, and a schedule of live training sessions;

b. the number of individuals required to participate in the training and complete the Acknowledgements required by Section III.C.4, the percentage of individuals who completed the training and Acknowledgements and an explanation for any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all Reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

7. Merck's response and corrective action plan(s) related to any issues raised in the reports prepared pursuant to Section III.D;

8. a summary and description of any and all current and prior engagements and agreements between Merck and the IRO, if different from what was submitted as part of the Implementation Certification;

9. a certification from the IRO regarding its professional independence and objectivity with respect to Merck;

10. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative actions

relating to all such Reportable Events;

11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

12. any changes to the process by which Merck fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and the actions taken by Merck in response to the screening and removal obligations set forth in Section III.F;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a description of all changes to the most recently provided list of Merck's locations (including addresses) as required by Section V.A.9; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Merck currently submits claims (if applicable); and

16. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Certification and Annual Reports shall include a certification by the Compliance Officer that:

1. he or she has reviewed the CIA in its entirety, understands the requirements described within, and maintains a copy of the CIA for reference;

2. to the best of his or her knowledge, except as otherwise described in the Implementation Certification or applicable Annual Report, Merck is in compliance with

all of the requirements of this CIA;

3. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

4. Merck has complied with its obligations under the Settlement Agreements: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreements, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreements); and (c) to identify and adjust any past charges or claims for unallowable costs;

5. all of Merck's: 1) Policies and Procedures referenced in Section III.B.4 above; 2) templates for standardized contracts and other similar documents; 3) training materials used for purposes of Section III.C, above; and 4) promotional materials used in connection with Government Reimbursed Products have been reviewed by competent legal counsel and have been found to be in compliance with the applicable Federal health care program requirements; and

6. Merck has provided to the OIG the Medicaid Drug Rebate certification as set forth in Appendix D covering the applicable Reporting Period(s) and such certification is true and correct in all respects.

D. Designation of Information. Merck shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Merck shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Merck:

Lucine Beauchard, Vice President
Office of Business Practices & Compliance
Merck & Co., Inc.
Mail Stop UG4B-35
351 N. Sumneytown Pike
North Wales, PA 19454
Telephone: 267.305.9267
Facsimile: 267.305.3093

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Merck's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Merck's locations for the purpose of verifying and evaluating: (a) Merck's compliance with the terms of this CIA; and (b) Merck's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Merck to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s)

may interview any of Merck's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Merck shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Merck's employees may elect to be interviewed with or without a representative of Merck present.

VIII. DOCUMENT AND RECORD RETENTION

Merck shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Merck prior to any release by OIG of information submitted by Merck pursuant to its obligations under this CIA and identified upon submission by Merck as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Merck shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Merck is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Merck and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to engage an IRO, as required in Section III.D and Appendices A-C.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to submit the Implementation Certification or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to submit the annual Merck or IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

5. A Stipulated Penalty of $1,500 for each day Merck fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Merck fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Merck as part of its Implementation Certification, Annual Report, additional documentation to supplement a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Merck fails to comply fully

and adequately with any obligation of this CIA. OIG shall provide notice to Merck, stating the specific grounds for its determination that Merck has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Merck shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Merck receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Merck may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Merck fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies any such timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Merck receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Merck has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Merck of: (a) Merck's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Merck shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Merck elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Merck cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach

of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Merck has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure by Merck to report a Reportable Event, take corrective action, and make any appropriate refunds, as required in Section III.H;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D and Appendices A-C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Merck constitutes an independent basis for Merck's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Merck has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Merck of: (a) Merck's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Merck shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Merck is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Merck has begun to take action to cure the material breach; (ii) Merck is pursuing such action with due diligence; and (iii) Merck has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Merck fails to satisfy the requirements of Section X.D.3, OIG may exclude Merck from participation in the Federal health care programs. OIG shall notify Merck in writing of its determination to exclude Merck (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Merck's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Merck may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Merck of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Merck shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the

request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Merck was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Merck shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Merck to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Merck requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Merck was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Merck had begun to take action to cure the material breach within that period; (ii) Merck has pursued and is pursuing such action with due diligence; and (iii) Merck provided to OIG within that period a reasonable timetable for curing the material breach and Merck has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Merck, only after a DAB decision in favor of OIG. Merck's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Merck upon the issuance of an ALJ's

decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Merck may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Merck shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Merck, Merck shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreements pursuant to which this CIA is entered, Merck and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Merck;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned Merck signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF MERCK & CO., INC.

Name: Bruce Kuhlik
Title: Executive Vice-President & General Counsel

Date: 2/5/08

Name: Lucine Beauchard
Title: Vice-President Global Support/U.S. Business Practices & Compliance

Date:

Name: Lisa Dykstra
Eric Holder
Counsel for Merck & Co., Inc.

Date: 2/5/08

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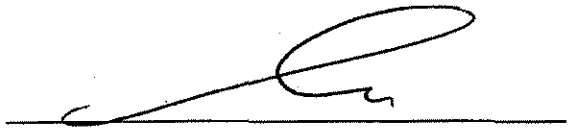
2/5/08

Date:

Name: Lisa Dykstra
Eric Holder
Counsel for Merck & Co., Inc.

Date:

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



2/5/08

Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A TO CIA FOR MERCK & CO., INC.

MEDICAID DRUG REBATE REVIEW

I. Medicaid Drug Rebate Review – General Description

As specified more fully below, Merck shall retain an Independent Review Organization (IRO) to perform reviews to assist Merck in assessing and evaluating its compliance with the requirements for Average Manufacturer Price (AMP) and Best Price (BP) under the Medicaid Drug Rebate Program. In order to conduct the Medicaid Drug Rebate Review, the IRO shall review samples of transactions to assess whether Merck is calculating AMPs and BPs consistent with the requirements of the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Review shall consist of two parts, the "AMP Reported Prices Procedures" and the "BP Reported Prices Procedures." The IRO shall conduct the Medicaid Drug Rebate Review annually.

II. Medicaid Drug Rebate Review

A. Party(ies) Conducting the Medicaid Drug Rebate Review

Merck annually conducts audits relating to Government Pricing and Contracting Functions, and Merck expects to continue such audits during the term of the CIA. At its option, Merck may provide a detailed description of its planned annual audits to the OIG 60 days prior to the beginning of each new Reporting Period. Merck may propose to the OIG that its planned internal audits be substituted for a portion of the Medicaid Drug Rebate Review outlined below in this Section II for the applicable Reporting Period.

If the OIG agrees to permit certain of Merck's internal audit work for a given Reporting Period to be substituted for a portion of the Medicaid Drug Rebate Review, such internal audit work would, at a minimum, be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional direction and specification about the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Merck in its internal audits and shall prepare a report based on its review.

The OIG retains sole discretion over whether to allow Merck's internal audit work to be substituted for a portion of the IRO's Medicaid Drug Rebate Review. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Merck's planned internal audit work, the results of the Medicaid

Drug Rebate Review(s) during prior Reporting Period(s), and Merck's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Merck's request to permit Merck's internal audit work to be substituted for a portion of the Medicaid Drug Rebate Review in a given Reporting Period, Merck shall engage the IRO to perform the Review as outlined below in this Section II.

B. General Description and Definitions

For each Reporting Period, the IRO shall select and review a sample of transactions from a randomly selected quarter within that Reporting Period to determine whether Merck calculated and reported AMP and BP consistent with the requirements of the Medicaid Drug Rebate Program. The selected quarter shall be identified through the use of the OIG's Office of Audit Services Statistical Sampling Software known as "RAT-STATS" or through the use of another method of random sampling acceptable to the OIG.

For purposes of the AMP Reported Prices Review, the following definitions shall apply:

1. "Actual Transaction Types" are defined as those transactions that are finalized at the time of the sale. As of the Effective Date, Merck had two categories of Actual Transaction Types, namely direct sales and on-invoice discounts. Each of these categories shall be considered a universe of Actual Transaction Types from which the IRO shall draw samples as detailed below in Section II.C.1. Each Transaction within the Actual Transaction Types group shall be referred to as an "Actual Transaction." If, during the term of the CIA, Merck establishes additional categories of Actual Transaction Types, each of the new categories shall be considered an additional universe of transactions from which samples of Actual Transactions shall be selected for purposes of the AMP Reported Prices Procedures.

2. "Lagged Transaction Types" are defined as those transaction types that are processed on a lagged basis. As of the Effective Date, Merck had two categories of Lagged Transaction Types, namely indirect sales, and adjustments or discounts available on a lagged basis. Each of these categories shall be considered a universe of Lagged Transaction Types from which the IRO shall draw samples as detailed below in Sections II.C.1. Each Transaction within the Lagged Transaction Types group shall be referred to as a "Lagged Transaction." If, during the term of the CIA, Merck establishes additional categories of Lagged Transaction Types, each of those new categories shall be considered an additional universe of

transactions from which samples of Lagged Transactions shall be selected for purposes of the AMP Reported Prices Procedures.

The Actual Transaction Types and Lagged Transaction Types shall be referred to hereafter as "Transaction Types".

C. AMP Reported Prices Procedures

1. Identification and Review of Transaction Types.

For each Reporting Period, the IRO shall review a sample of transactions to determine whether Merck calculated and reported AMP in accordance with the requirements of the Medicaid Drug Rebate Program (AMP Reported Prices Procedures). The IRO shall conduct its AMP Reported Prices Procedures by selecting and testing samples from each universe of the applicable Transaction Types, as identified by Merck, for the selected quarter within the Reporting Period. The IRO shall test a discovery sample of 30 Transactions from each universe of Transaction Types for the selected quarter.

a) Actual Transactions

For each universe of Actual Transaction Types, the IRO shall randomly select a discovery sample and, with regard to the sample, shall determine:

i) Whether the Actual Transactions are supported by source documents; and

ii) Whether Merck included or excluded each Actual Transaction in the AMP calculation in accordance with Medicaid Drug Rebate Program requirements.

b) Lagged Transactions

For each universe of Lagged Transaction Types, the IRO shall randomly select a discovery sample and, with regard to the sample, shall determine:

i) Whether the Lagged Transaction amounts were calculated in accordance with Merck's policies, procedures, and methodologies and (where applicable) the Medicaid Drug Rebate Program requirements, and were supported by

relevant commercial arrangements or other source documentation; and

ii) Whether the Lagged Transactions were included in or excluded from the AMP calculation in accordance with Medicaid Drug Rebate Program requirements.

2. Additional Investigation of Transactions

If any discovery sample defined in Section II.C.1 reveals a net dollar Error Rate of 5% or greater, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings. The IRO shall present its findings, Merck shall present its management response, and the OIG shall review and consider the information provided by the IRO and Merck. Following consultations with Merck and the IRO, the OIG, in its discretion, shall determine whether an Additional Investigation shall be required. For any required Additional Investigation, the IRO shall review additional documentation and/or conduct additional interviews with appropriate personnel, as necessary, to identify the root cause of the net Error Rate.

Upon review of the discovery sample and any Additional Investigation, if warranted, for each universe of Transaction Types, the IRO shall report its findings to the OIG and Merck.

In its discretion, the OIG will determine whether the review of a statistically valid random sample of additional Transactions from the applicable universe shall be required and the size of that statistically valid random sample. The OIG shall base these determinations on discussions with the IRO and Merck, the results of the IRO's reviews of discovery samples, and the findings of any Additional Investigation that may have been deemed warranted.

The discovery samples (and additional samples that may be required) shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS" or through the use of another method of random sampling acceptable to the OIG.

D. BP Reported Prices Procedures

For each Reporting Period, the IRO shall conduct BP Reported Prices Procedures to determine whether Merck calculated and reported BP in accordance with the requirements of the Medicaid Drug Rebate Program.

The BP Reported Prices Procedures shall consist of two parts:

1. Part One of BP Reported Prices Procedures

Merck shall provide the IRO with a list of all Merck Customers who purchased or contracted for Medicaid rebate eligible products during the selected quarter of the Reporting Period. The IRO shall randomly select a sample of 20 Merck Customers using the following methodology. The IRO shall aggregate the number of NDCs[1] for each Merck Customer and shall categorize each Merck Customer as "large" or "small" based upon the total volume of sales[2] of the contracted Medicaid rebate eligible NDCs to that Merck Customer in the selected quarter of the Reporting Period. The IRO shall randomly select 15 Merck Customers from the large Merck Customer category and 5 Merck Customers from the small Merck Customer category.

For each of the "large" and "small" Merck Customers identified by the IRO, the IRO's review shall cover the fifteen NDCs for which Merck paid the largest amount (i.e., total dollars) of Medicaid rebates during the Reporting Period and five randomly selected NDCs (collectively, the "Selected BP NDCs"). However for purposes of determining the Selected BP NDCs, if Merck paid less than $20,000 in Medicaid rebates during the Reporting Period for any randomly selected NDC, the IRO will replace that NDC with a randomly selected NDC for which Merck paid at least $20,000 in Medicaid rebates for the Reporting Period.

For each Merck Customer selected, the IRO shall identify all contracts with Merck and all corresponding Medicaid rebate eligible NDCs for which the Merck Customer had a contract price with Merck. The IRO shall determine whether the contract price for each Selected BP NDC for products sold to the Merck Customer is accurately reflected in Merck's systems relevant for purposes of determining BP. The IRO shall determine whether the contract price is appropriately considered for purposes of determining BP in accordance with the requirements of the Medicaid Drug Rebate Program.

[1] For purposes of this Appendix A, "NDC" means a single dosage, form, and strength of a pharmaceutical product, without regard to package size (i.e., NDC 9).

[2] For purposes of this Section II.D, "volume of sales" means for the most recent quarter for which complete data is available: (i) net sales before government rebates; or (ii) for managed care and other similar entities, utilization.

Merck shall also provide the IRO with information and documentation about all non-price-related arrangements or relationships initiated during the Review Period between Merck and the "large" and "small" Merck Customers identified by the IRO ("Other Arrangements"). These Other Arrangements could include, by way of example only, grants provided to the Merck Customer or data or service fee arrangements entered with the Merck Customer. The IRO shall review documentation and information about the Other Arrangements sufficient to identify the nature of the Other Arrangements, describe the terms of the Other Arrangements (including any amounts paid or other benefits conferred by Merck in connection with the Other Arrangements and the time periods of the arrangements), and identify any NDCs and/or Merck drugs that were the subject of the Other Arrangements.

2. Part Two of BP Reported Prices Procedures

Merck shall provide the IRO with the following information:

a) a listing of the ten Medicaid rebate eligible NDCs for which Merck paid the largest amount (i.e., total dollars) of Medicaid rebates during the Reporting Period; and

b) for each of the ten Medicaid rebate eligible NDCs selected, a listing of all unique prices paid to Merck for the product that were lower than the reported BP for the selected quarter.

For each unique price that was lower than the reported BP, the IRO shall review a minimum of five randomly selected contracted transactions associated with each of those unique lower prices (or, if there are fewer than five such transactions, all such transactions) to determine whether each was properly excluded from the determination of BP for that Medicaid rebate eligible NDC in accordance with Medicaid Drug Rebate Program requirements.

3. Additional Investigations

If the BP Reported Prices Procedures reveal any prices that were not accurately reflected in Merck's systems and/or were not appropriately included in, or excluded from, Merck's BP determination in accordance with Medicaid Drug Rebate Program requirements, such prices shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to

determine the root cause of the error. For example, the IRO may need to review additional documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

Upon completion of these reviews and any Additional Investigation(s) that may have been warranted, the IRO shall report its findings to the OIG.

In the event the IRO discovers more than one error for the quarter under review in Part One or Part Two of the BP Reported Prices Procedures, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings. The IRO shall present its findings, Merck shall present its management response, and the OIG shall review and consider the information provided by the IRO and Merck. Following consultations with Merck and the IRO, the OIG, in its discretion, shall determine whether further review is warranted. Should the OIG determine that further review is warranted, the IRO shall randomly select and review a second sample as set forth below in this Section II.D.3, using the same seed number, and repeat Part One and/or Part Two of the BP Reported Prices Procedures (depending on whether one or both parts of the BP Reported Prices Procedures warranted an Additional Investigation).

Should the OIG determine that further review is warranted, the IRO shall:

a) If additional Part One review is required, randomly select five additional Merck Customers from the large Merck Customer category; and/or

b) If additional Part Two review is required, review the next five Medicaid rebate eligible NDCs for which Merck paid the largest amount (i.e., total dollars).

E. Medicaid Drug Rebate Review Report

1. General Requirements

The IRO shall prepare a report annually based upon each Medicaid Drug Rebate Review performed. The report shall contain the following general elements pertaining to both the AMP Reported Prices Procedures and the BP Reported Prices Procedures:

a) Medicaid Drug Rebate Review Objective(s) – a clear statement of the objective(s) intended to be achieved by each engagement;

b) Testing Protocol – a detailed narrative description of: (i) the procedures performed; (ii) the sampling units; and (iii) the universe from which the sample was selected; and

c) Sources of Data – a full description of documentation and/or other relevant information relied upon by the IRO when performing the reviews.

The IRO shall also include the following information in each Medicaid Drug Rebate Review Report:

2. AMP Reported Prices Procedures

a) A description of Merck's methodology for calculating AMP as reported for purposes of the Medicaid Drug Rebate Program, including its methodology for determining which classes of trade and types of transactions are included or excluded for purposes of calculating AMP;

b) For each universe of Transaction Types tested, the IRO shall state its findings and supporting evidence as to whether the Transaction Types reviewed satisfied the corresponding criteria outlined above in Section II.C.1;

c) For each universe of Transaction Types tested, the IRO shall specify the net Error Rate discovered;

d) For each universe of Transaction Types for which the OIG determined that an Additional Investigation was required, the IRO shall explain its findings and describe supporting evidence;

e) For each universe of Transaction Types for which the IRO conducted a review on a second statistically valid sample as discussed in Section II.C.2, the IRO shall explain its findings and describe supporting evidence; and

f) The IRO shall report any recommendations for changes to Merck's policies, procedures, and/or methodologies to correct or address any

weaknesses or deficiencies discovered during the AMP Reported Prices Procedures.

3. BP Reported Prices Procedures – Part One

   a) a description/identification of the following: (i) the 20 Merck Customers selected under Part One; (ii) the number of contracts associated with each Merck Customer; (iii) the Selected BP NDCs tested; (iv) the contract prices for each NDC tested; and (v) a description of any supporting documentation reviewed;

   b) a description of the IRO's stratification system for identifying the "large" and "small" Customers and documentation supporting the random selection of the Customers;

   c) for each selected Merck Customer, a description of the steps taken to determine whether the contract price(s) for each Selected BP NDC was (were) accurately reflected in Merck's systems;

   d) for each selected Merck Customer, the IRO's determination regarding whether each Selected BP NDC contract price was accurately reflected in Merck's contracting systems. If the correct price was not reflected in the systems, the IRO should identify the correct price;

   e) a detailed description of any Additional Investigation or further review undertaken with regard to any Selected BP NDC price not accurately reflected in Merck's systems and the results of any Additional Investigation or further review undertaken with respect to any such price;

   f) for each selected Merck Customer, a description of the steps taken to determine whether each contract price(s) was (were) appropriately considered in Merck's determination of the BPs for the Select BP NDCs in accordance with Medicaid Drug Rebate Program requirements;

   g) for each selected Merck Customer: (i) a list of any price not properly included in, or excluded from, Merck's BP determination for the applicable quarter; (ii) a description of any adjustments to BP reported to CMS; and (iii) a description of any additional follow-up action taken by Merck;

h) a detailed description of any Additional Investigation or further review undertaken with regard to any price not appropriately included in, or excluded from, Merck's BP determination for the selected quarter, and the results of any Additional Investigation or further review undertaken with respect to any such price;

i) for each selected Merck Customer: (i) a description of the nature of all Other Arrangements entered between Merck and the Merck Customer; (ii) a description of the terms of all Other Arrangements (including any amounts paid or other benefits conferred by Merck in connection with the Other Arrangements and the time periods of the arrangements); (iii) an identification of any NDCs and/or Merck drugs that were the subject of the Other Arrangements; and (iv) a description of the documentation or information reviewed with regard to all Other Arrangements; and

j) the IRO's recommendations for changes in Merck's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies discovered during the review.

4. BP Reported Prices Procedures – Part Two

a) a list of: (i) the ten Medicaid rebate eligible NDCs with the highest rebates paid by Merck during the Reporting Period; (ii) the BP reported by Merck to CMS for the Medicaid Drug Rebate Program for each of the ten NDCs under review; and (iii) a description of the underlying documentation supporting the random selection of the five contacted transactions associated with each unique price lower than the reported BPs;

b) a description of the steps and the supporting documentation reviewed to assess the unique lower prices for each of the selected NDCs which were below the BPs reported by Merck to CMS. If more than five contracted transactions are associated with any of the unique lower prices, the IRO shall also identify how many such transactions exist for each unique lower price;

c) a list of any prices not properly excluded from Merck's BP determination for any of the ten NDCs reviewed; a description of any adjustments to BP reported to CMS; and a description of any additional follow-up action taken by Merck for any of the ten NDCs reviewed;

d) a detailed description of any Additional Investigation or further review undertaken with regard to any prices that were not properly excluded from Merck's BP determination for any of the ten NDCs reviewed and the results of any such Additional Investigation or further review; and

e) the IRO's recommendations for changes in Merck's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies discovered during the review.

APPENDIX B TO CIA FOR MERCK & CO., INC.

Promotional and Product Services Review

I. Promotional and Product Services Review, General Description

As specified more fully below, Merck shall retain an Independent Review Organization (IRO) to perform reviews to assist Merck in assessing and evaluating its systems, processes, policies, procedures, and practices related to Merck's Promotional and Product Services Related Functions (Promotional and Product Services Review). The Promotional and Product Services Review shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (the Promotional and Product Services Transactions Review), as described more fully below. Merck may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Review, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Merck's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Merck materially changes its systems, processes, policies, and/or procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether there were any material changes in other systems, processes, policies, and/or procedures previously reviewed and reported; and 3) a review of the systems, processes, policies, and procedures that materially changed. Subject to the provisions relating to internal audits by Merck as set forth in Section III.D.2 of the CIA and Section III of this Appendix, the IRO shall conduct the Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Merck's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Promotional and Product Services Related Functions. Where practical, Merck personnel may

compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Merck pursuant to the preceding sentence.

In conducting the Promotional and Product Services Systems Review, the IRO shall review Merck's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Merck's systems, policies, processes, and procedures relating to the retention of health care practitioners (HCPs) or health care institutions (HCIs) as consultants in support of Promotional and Product Services Related Functions (e.g., including, but not limited to, for purposes of advisory boards, expert input forums, thought leader market research, speakers, or other fee-for-service arrangements.) This shall include a review of:

a) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) Merck will enter such consultant arrangements and the business rationale for entering consultant arrangements;

b) the processes and criteria used to identify and select HCPs and HCIs with whom Merck enters consultant arrangements, including the role played by sales representatives or field personnel in the process (if any). This includes a review of Merck's internal review and approval process for such arrangements, and the circumstances under which there may be exceptions to the process;

c) Merck's systems, policies, processes, and procedures for tracking or monitoring the services provided or the work performed under consultant arrangements (including the receipt of the work product received from the HCPs or HCIs, if any);

d) Merck's policies and procedures related to any requirement that the HCPs or HCIs (or their agents) disclose the existence of their consultant arrangements with Merck and any financial relationship the HCP or HCI has with Merck;

e) Merck's systems, policies, processes, and procedures for ensuring and verifying that the work product

received from the HCPs or HCIs is used by the Company;

f) Merck's processes for establishing the amounts paid to HCPs or HCIs under consultant arrangements and the reasons or justifications for any differentials in the amounts paid to different HCPs and HCIs;

g) the criteria used to determine under what circumstances meals, travel, lodging, entertainment, gifts, and/or other items or reimbursements are provided to the HCPs or HCIs in connection with the consultant arrangements, and Merck's policies for establishing the amounts paid or reimbursed for such items;

h) Merck's systems, policies, processes, and procedures relating to whether (if at all) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consulting arrangements; and

i) the budget funding source within Merck (e.g., department or division) for the consulting arrangements;

2) Merck's systems, policies, processes, and procedures relating to Merck's Medical Forums (MMFs) (which are medical education programs facilitated by speakers under contract with Merck) (including peer discussion group, lecture, symposium, E-Medical Forum (eMF) and Physician Facilitated Interaction activities). This review shall include a review of the following items:

a) the processes and procedures used to approve the funding or sponsorship of any MMF activity;

b) the criteria used to determine whether and under what circumstances the funding or sponsorship will be provided;

c) the processes and criteria used to select participants (including the speakers/moderators/facilitators of the MMFs and attendees at the MMFs), including the role played by sales representatives or field personnel in the processes (if any), and the circumstances under which there may be exceptions to the processes;

d) Merck's policies and procedures relating to any requirements that speakers/moderators/facilitators of MMFs disclose Merck's funding or sponsorship and

any financial relationship Merck may have with the speaker/moderator/facilitator;

e) Merck's policies or procedures for determining and memorializing the amounts paid to speakers/moderators/facilitators and the purpose or justifications for the amounts paid, including any differentials in amounts paid to different speakers/moderators/facilitators;

f) Merck's policies and procedures relating to the limitations on the number of times in a calendar year that a speaker/moderator/facilitator may be used for an MMF or other Merck-sponsored activity;

g) Merck's policies and procedures relating to the content and nature (e.g., promotional, non-promotional) of any MMFs;

h) the criteria used to determine under what circumstances meals, travel, lodging, gifts, and/or other items or reimbursements are provided in connection with the MMFs, and Merck's policies for establishing the amounts paid or reimbursed for such items;

i) Merck's systems, policies, processes, and procedures relating to whether (if at all, for each type of individual or entity) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities participating in the MMFs (either as attendees or as speakers/moderators/facilitators); and

j) the budget funding source within Merck (e.g., department or division) from which the funding for MMFs are provided;

3) Merck's systems, policies, processes, and procedures relating to funding of, sponsorship of, or participation in field-based-employee (FBE) facilitated meetings (including, but not limited to, in-office and out-of-office facilitated meetings, business and other meetings over meals, displays over meals, and external journal clubs) and field directed exhibits/displays (collectively "FBE Activities"). This review shall include a review of the following items:

a) the processes and procedures used to approve the funding or sponsorship of, or participation in, FBE Activities;

b) the criteria used to determine whether and under what circumstances Merck will fund, sponsor, or otherwise participate in FBE Activities;

c) the processes and criteria used to select recipients of the funding for the FBE Activities, including the role played by field personnel or sales representatives in the processes, and the circumstances under which there may be exceptions to the processes;

d) Merck's policies and procedures relating to any requirement that Merck or the recipient of the FBE Activity funding or sponsorship disclose Merck's funding and any financial relationship Merck may have with the recipient;

e) Merck's policies or procedures for determining and memorializing the amounts paid in connection with the FBE Activities and the purpose or justifications for the amounts paid;

f) the criteria used to determine under what circumstances meals, gifts, and/or other items or reimbursements are provided in connection with the FBE Activities, and Merck's policies for establishing the amounts paid or reimbursed for such items;

g) Merck's systems, policies, processes, and procedures relating to whether (if at all) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities receiving the FBE Activities funding or sponsorship; and

h) the budget funding source within Merck (e.g., department or division) for the Research Activities;

4) Merck's systems, policies, processes, and procedures relating to grants administered by Merck's Academic Affairs department (including, but not limited to, CE/CME Grants, Patient Advocacy Group Grants, and Professional Society Grants.) This review shall include a review of the following items:

a) the processes and procedures used to approve grants;

b) the criteria used to determine whether and under what circumstances Merck will provide grants;

c) the processes and criteria used to select grant recipients, including the role played by field personnel or sales representatives in the processes (if any), and

the circumstances under which there may be exceptions to the processes;

d) Merck's policies and procedures relating to any requirement that the grant recipient (or the recipient's agent) disclose the grant and any financial relationship Merck may have with the recipient;

e) Merck's policies or procedures for determining and memorializing the grant amounts and the purpose or justifications for the amounts paid;

f) Merck's policies and procedures relating to the independence of any programs funded through the grants;

g) Merck's policies and procedures relating to the content and nature (e.g., promotional, non-promotional) of any programs funded through grants;

h) Merck's systems, policies, processes, and procedures relating to whether (if at all) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities receiving the grants; and

i) the budget funding source within Merck (e.g., department or division) for the grants;

5) Merck's systems, policies, processes, and procedures for tracking expenditures (individual and aggregate) associated with the Reviewed Policies and Procedures referenced in Sections II.A.1-4, above;

6) Merck's policies, processes, and procedures relating to disciplinary actions that Merck may undertake in the event a Covered Person violates a Merck policy or procedure relating to Promotional and Product Services Related Functions; and

7) Merck's systems, polices, processes, and procedures relating to compensation arrangements (including salaries and bonuses) for Relevant Covered Persons engaged in Promotional and Product Services Related Functions, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not motivate such individuals to engage in such Functions in an improper manner. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of Merck's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-7 above, including a general description of Merck's control and accountability systems (e.g., documentation and approval requirements, tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-7 above are made known or disseminated within Merck;

4) a description of Merck's systems, policies, processes, and procedures for tracking any expenditures associated with the Reviewed Policies and Procedures referenced in Sections II.A.1-4, above;

5) a general description of Merck's disciplinary measures applicable for a failure to comply with its policies and procedures relating to Promotional and Product Services Related Functions;

6) a detailed description of Merck's compensation system (including salaries and bonuses) for Relevant Covered Persons engaged in Promotional and Product Services Related Functions, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Merck may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

7) findings and supporting rationale regarding any weaknesses in Merck's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

8) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. Promotional and Product Services Transaction Review

Merck annually conducts audits relating to Promotional and Product Services Related Functions, and Merck expects to continue such audits during the term of the CIA. At its option, Merck may provide a detailed description of its planned annual audits to the OIG 60 days prior to the beginning of each new Reporting Period. Merck may propose to the OIG that its planned internal audits be substituted for a portion of the Promotional and Product Services Transactions Review outlined below in this Section III for the applicable Reporting Period.

If the OIG agrees to permit certain of Merck's internal audit work for a given Reporting Period to be substituted for a portion of the Promotional and Product Services Transaction Review, such internal audit work would, at a minimum, be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional direction and specification about the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Merck in its internal audits and shall prepare a report based on its review.

The OIG retains sole discretion over whether to allow Merck's internal audit work to be substituted for a portion of the Promotional and Product Services Transactions Review. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Merck's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Merck's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Merck's request to permit Merck's internal audit work to be substituted for a portion of the Promotional and Product Services Review in a given Reporting Period, Merck shall engage the IRO to perform the Review as outlined below in this Section III.

A. Promotional and Product Services Transactions Review

1) Background on Policies and Merck Activities

Merck has developed policies and procedures relating to programs and activities with HCPs and others that may be initiated by its field-based employees or by its headquarters personnel.

The activities initiated and handled by headquarters personnel include consulting activities and grants. These programs are initiated and handled by Merck's Marketing department and Merck's Academic Affairs department, respectively. More specifically, Merck's Marketing department initiates consultant activities including: Advisory Boards, Thought Leader Market Research activities, and Expert Input Forums. These activities shall be referred to collectively as "Consulting Activities."

Merck's Academic Affairs department evaluates and administers all CE/CME grants, Patient Advocacy Group Grants, and Professional Society Grants. These activities shall be referred to collectively known as "Grants".

The activities primarily initiated and handled by field based-employees U.S. Pharma fall into three general categories: facilitated meetings, field directed exhibits/displays, and speaker-facilitated programs (also known as Merck Medical Forums (MMFs).) Facilitated meetings are informal meetings that provide a setting for clinical and/or product discussions with a small group of HCPs that are facilitated by Merck field-based employees. MMFs include peer discussion groups, lectures, physician facilitated interactions, symposium, and eMedical forums. Certain Merck headquarters personnel are also involved with MMF activities. The facilitated meetings, field directed exhibits/displays, and MMFs shall be referred to collectively as "Field Activities".

For purposes of the Promotional and Product Services Transactions Review, Consulting Activities, Grants, and Field Activities shall each be a universe from which samples of activities shall be drawn and reviewed by the IRO. Consulting Activities, Grants, and Field Activities shall be referred to collectively as "Reviewed Activities".

2) Description of Reviewed Activities Control Documents and Selection of Samples for Review

"Control Documents" shall be defined to include all documents or electronic records (collectively "documents") associated with each set of Reviewed Activities. These documents include, but are not limited to, all documents submitted by sales representatives or headquarters personnel to request approval for the Reviewed Activity; business rationale or justification forms; written contracts relating to the Reviewed Activity; all documents relating to the

occurrence of the Reviewed Activity (*e.g.*, attendance rosters, receipts); and all documents reflecting any work product generated in connection with the Reviewed Activity.

For each Transactions Review, the IRO shall review a total of 90 distinct Reviewed Activities that occurred during the relevant Reporting Period. For each Reporting Period, the OIG, in its discretion, shall identify the number and type(s) of Reviewed Activities from each of the three universes (Consulting Activities, Grants, and Field Activities) to be reviewed by the IRO. For example, the OIG may determine that for a particular Reporting Period, the IRO's review shall include 30 Grants, and that the Grants-related review shall encompass 15 CME/CE Grants and 15 Professional Society Grants.

In order to aid the OIG in making its determinations about the number and types of Reviewed Activities, no later than 120 days prior to the start of each Reporting Period, Merck shall provide the OIG with certain information. Specifically, Merck shall provide information about the estimated number of each type of Reviewed Activities that occurred (or will occur) during the preceding Reporting Period and the amount of spending associated with each type of Reviewed Activity. The OIG shall make its determination about the number and types of Reviewed Activities to be reviewed from each of the three universes after reviewing the information provided by Merck and after consultation with Merck.

After making its determinations, the OIG shall notify Merck about the number and type(s) of Reviewed Activities that shall be reviewed from each of the three universes as part of the Transactions Review. Based on the OIG's determinations, the IRO shall randomly select the appropriate number of occurrences of each specified type of Reviewed Activities from the three universes. The IRO shall review all Control Documents associated with the selected sample of Reviewed Activities.

For each sampled Reviewed Activity, the IRO shall review the associated Control Documents to evaluate the following:

a) Whether all required Control Documents exist in appropriate files in accordance with Merck's policies and procedures;

b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Merck's policies and procedures; and

c) Whether the Control Documents reflect that Merck's policies and procedures were followed in connection with the underlying activities (*e.g.*, all required written approvals for the activity were obtained in accordance with Merck's policies.)

3) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

a) All required Control Documents relating to a Reviewed Activity do not exist and:
   i. no corrective action was initiated prior to the selection of the Reviewed Activities by the OIG; or
   ii. the IRO cannot confirm that Merck otherwise followed its policies and procedures relating to the Reviewed Activity.

b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Merck's policies and procedures and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Merck initiated corrective action prior to the sample selection of the Reviewed Activities by the IRO, or if a Control Document does not exist but the IRO can determine that Merck otherwise followed its policies and procedures with regard to the Reviewed Activity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Reviewed Activities associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

B. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall include the following:

1) General Elements to Be Included in Report

a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report:

a) a description of each type of sample unit reviewed for each Reviewed Activity, including the number of each type of sample units reviewed (*e.g.*, Control Documents associated with each of the various types of Reviewed Activities) and an identification of the types of Control Documents reviewed for each type of sample unit;

b) for each sample unit, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed and archived in accordance with all of the requirements set forth in the applicable Merck policies and procedures; (iii) each Control Document reflects that Merck's policies and procedures were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and (iv) any disciplinary action was undertaken in those instances in which Merck policies and procedures were not followed;

c) for each sample unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

d) if any Material Errors are discovered in the sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error; and

e) recommendations, if any, for changes in Merck's systems, processes, policies, and procedures to correct or address any weaknesses or deficiencies uncovered during the Transactions Review. The report shall include findings and supporting rationale for all such recommendations.

APPENDIX C TO CIA FOR MERCK & CO., INC.

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

Merck shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Merck if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Merck may continue to engage the IRO.

If Merck engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Merck shall submit the information identified in Section V.A.6 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Merck if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Merck may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Medicaid Drug Rebate Reviews and the Promotional and Product Services Reviews who have expertise in all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions and Promotional and Product Services Related Functions and in the general requirements of the Federal health care program(s) under which Merck's products are reimbursed;

2. assign individuals to the Medicaid Drug Rebate Review and the Promotional and Product Services Review who are knowledgeable about appropriate techniques required for the Reviews, including assigning individuals who are knowledgeable about appropriate statistical sampling techniques to design and select samples for the Transaction Reviews; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Medicaid Drug Rebate Review and Promotional and Product Services Review in accordance with the specific requirements of the CIA, including Appendices A-B, as applicable;

2. follow all applicable Federal health care program requirements in making assessments in each Medicaid Drug Rebate Review and Promotional and Product Services Review;

3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., CMS);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices A and B.

D. IRO Independence and Objectivity.

The IRO must perform each Medicaid Drug Rebate Review and Promotional and Product Services Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Merck.

E. IRO Removal/Termination.

1. *Provider*. If Merck terminates its IRO during the course of the engagement, Merck must submit a notice explaining its reasons to OIG no later than 30 days after termination. Merck must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO*. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Merck to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Merck to engage a new IRO, OIG shall notify Merck of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Merck may request a meeting with OIG to

discuss any aspect of the IRO's qualifications, independence, or performance of its responsibilities and to present additional information regarding these matters. Merck shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Merck prior to requiring Merck to terminate the IRO. However, the final determination as to whether or not to require Merck to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX D TO CIA FOR MERCK & CO., INC.

Certification

In accordance with the Corporate Integrity Agreement (CIA) entered between Merck and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information, and belief:

1) Merck has in place policies and procedures describing in all material respects its methods for collecting, calculating, verifying, and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate Program (Medicaid Rebate Policies and Procedures);

2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with Merck's obligations under the Medicaid Drug Rebate Program;

3) Merck's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Price (AMP) and Best Price (BP) for Merck's products for each of the below-listed four quarters: [specifically identify the applicable quarters]; and

4) the AMPs and BPs reported to CMS in the above-listed quarters were calculated accurately and all information and statements made in connection with the submission of AMPs and BPs and in this Certification are true, complete, and current and are made in good faith.

_____
Signature

_____
Name of CEO, CFO, or other appropriate individual consistent with 42 C.F.R. § 447.510(e)

_____
Date

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America, et al., ex rel. Ronald E. Kavanagh

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
John Roddy, Bailey & Glasser LLP
125 Summer Street, Suite 1030
Boston, MA 02110 617.439.6730 ext. 1602

DEFENDANTS

Merck & Co., Inc., Schering-Plough, Organon, N.V., Azko Nobel, N.V., Pfizer, Inc., Johnson and Johnson, and Eli Lilly & Co.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff) and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☒ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
31 U.S.C. § 3729, et seq.

Brief description of cause:
False Claims Act case alleging Defendants obtained fraudulent FDA approval of their drugs.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
12/07/2012

SIGNATURE OF ATTORNEY OF RECORD
John Roddy

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** United States ex rel. Kavanagh v. Merck & Co., Inc.

2. **Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).**

☐ **I.** **410, 441, 470, 535, 830*, 891, 893, 895, R.23, REGARDLESS OF NATURE OF SUIT.**

☐ **II.** **110, 130, 140, 160, 190, 196, 230, 240, 290,320,362, 370, 371, 380, 430, 440, 442, 443, 445, 446, 448, 710, 720, 740, 790, 820*, 840*, 850, 870, 871.**

☑ **III.** **120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 367, 368, 375, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 625, 690, 751, 791, 861-865, 890, 896, 899, 950.**

***Also complete AO 120 or AO 121. for patent, trademark or copyright cases.**

3. **Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.**

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**

YES ☐ **NO** ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**

YES ☐ **NO** ☑

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES ☐ **NO** ☐

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**

YES ☐ **NO** ☑

7. **Do <u>all</u> of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**

YES ☐ **NO** ☑

A. **If yes, in which division do <u>all</u> of the non-governmental parties reside?**

Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

B. **If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?**

Eastern Division ☑ **Central Division** ☐ **Western Division** ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**

YES ☐ **NO** ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME John Roddy

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TELEPHONE NO. (617) 439-6730 ext. 1602