UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF FLORIDA, and STATE OF NEW JERSEY, *ex rel*., PAUL DENIS, Plaintiffs, v. MEDCO HEALTH SOLUTIONS, INC., and EXPRESS SCRIPTS HOLDING COMPANY, Defendants.	)	Civil Action No.: 11-684 (RGA) **THIRD AMENDED COMPLAINT** **DEMAND FOR JURY TRIAL**

TABLE OF CONTENTS

I. INTRODUCTION 1

A. Federal Law Claims 1

B. State Law Claims 1

II. SUMMARY OF THE ALLEGATIONS 2

III. JURISDICTION AND VENUE 9

IV. THE PARTIES 11

V. GOVERNING LAWS, REGULATIONS AND CODES OF CONDUCT 13

A. The Federal False Claims Act 13

B. The State False Claims Acts 14

C. Federal Government-Funded Health Assistance Programs 15

1) Medicare 15

2) Medicaid 17

D. Applicable Provisions 18

1) The Anti-Kickback Statute 18

2) Prohibitions Against Claims for Services that are Not Medically Necessary or are Otherwise False or Fraudulent 20

E. State Government-funded Healthcare Plans 20

1) California 20

2) Florida 20

3) New Jersey 21

VI. SPECIFIC ALLEGATIONS 21

A. Medco and the Pharmacy Benefit Management Business 21

B. Medco's Fraudulent Actions 23

1) The Corporate Integrity Agreement and Rebate Agreements 23

2) The AstraZeneca Agreements 24

3) At Medco's Request AstraZeneca Agreed to Conceal Rebates in Secret Agreements 26

4) Medco's Actions Constitute Violations of the Anti-Kickback Statute and the False Claims Act 34

5) Medco's Actions Submitted in connection with Part D Violated the FCA 36

6) Medco's Actions In Connection With the RDS Program Violated the FCA 36

7) Medco's Actions Constitute Violations of the State False Claims Acts 37

C. Damages Caused by Medco's Unlawful Scheme 38

VII. CLAIMS FOR RELIEF 40

FIRST CAUSE OF ACTION 40

SECOND CAUSE OF ACTION 41

THIRD CAUSE OF ACTION 41

FOURTH CAUSE OF ACTION 41

FIFTH CAUSE OF ACTION 42

SIXTH CAUSE OF ACTION 42

SEVENTH CAUSE OF ACTION 43

EIGHTH CAUSE OF ACTION 44

VIII. DEMANDS FOR RELIEF 45

TRIAL BY JURY 46

On behalf of the United States of America, the State of California, the State of Florida, and the State of New Jersey, Plaintiff and Relator Paul Denis ("Relator") files this third amended *qui tam* complaint against Defendant Medco Health Solutions, Inc. and Express Scripts Holding Company (collectively "Medco" or "Defendants") and alleges as follows:

I. INTRODUCTION

A. Federal Law Claims

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America in connection with Medco's defrauding of the United States Government by seeking and accepting kickbacks in the form of undisclosed purchase discounts from drug manufacturers in violation of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), and in violation of the Corporate Integrity Agreement ("CIA") entered into between Medco and the Office of Inspector General of the Department of Health and Human Services and the Office of Inspector General of the Office of Personnel Management, and failing to inform its clients of these undisclosed purchase discounts, thereby both defrauding those clients, and unlawfully inflating the payments made by the federal government under the Medicare Voluntary Prescription Drug Benefit Program ("Medicare Part D" or "Part D").

2. Pursuant to the FCA, Relator seeks to recover, on behalf of the United States of America, damages and civil penalties arising from false or fraudulent claims that Defendant submitted or caused to be submitted to the United States Government, most significantly reimbursements or subsidies made by the Federal Government pursuant to Medicare Part D.

B. State Law Claims

3. This is also an action to recover double and treble damages and civil penalties on behalf of the named States arising from the conduct of Defendant who: (a) made, used or

presented, or caused to be made, used or presented, certain false or fraudulent statements, records and/or claims for payment or approval to the States; and/or (b) made, used or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the States, all in violation of each State's respective false claims act or similar statute. The false or fraudulent claims, statements and records at issue involve payments made by health insurance programs funded by these State governments, including Medicaid.

4. The statutes of the States under which Relator brings this action are the:

a. California False Claims Act, Cal. Govt. Code §§ 12651, *et seq.*;

b. Florida False Claims Act, Fla. Stat. Ann. §§ 68.081, *et seq.*; and

c. New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*

II. SUMMARY OF THE ALLEGATIONS

5. Medco has defrauded the Government by seeking and accepting kickbacks in the form of hidden discounts in confidential agreements from pharmaceutical manufacturers including the manufacturer AstraZeneca in exchange for favoring certain AstraZeneca drugs, failing to share those discounts with its clients, including Medicare Part D participants, and not abiding by the Defendant's Corporate Integrity Agreement ("CIA") with the United States Government.

6. Medco's clandestine arrangement with AstraZeneca allowed it to retain hundreds of millions of dollars in manufacturer discounts which would otherwise have been shared with Medco's clients, including state and privately sponsored employer health care plans that receive subsidies from the federal government under Medicare Part D, and Medicare Part D plan sponsors ("Part D Plan Sponsors"), such as Medicare-Advantage prescription drug ("MA-PD") plan sponsors, private prescription drug plan ("PDP") sponsors, and Employer Group Waiver

Plan ("EGWP") sponsors, to which the Government makes payments on behalf of participating Part D beneficiaries.

7. Medco Health Solutions has for decades been one of the largest Pharmacy Benefit Management ("PBM") companies in the United States, with net revenues of $51.3 billion in 2008, $59.8 billion in 2009, $66 billion in 2010, and $70.1 billion in 2011. In 2012, subsequent to its merger with Express Scripts Inc. under the banner of Express Scripts Holding Company, the combined company's 2012 revenue was $93.9 billion dollars.

8. Pharmacy Benefit Managers contract with clients such as government entities, health plans, employers, unions, and managed care organizations to administer pharmacy benefits. Services provided by PBMs include processing pharmacy claims, assisting with the development of drug plan designs, developing formularies, negotiating rebates from pharmaceutical manufacturers, and providing retail pharmacy networks and mail-order pharmacies for clients. State health plans and unions, such as those in California, Florida, and New Jersey, contract with and utilize the pharmacy benefits provided by Medco and Express Scripts.

9. Medco's clients are mostly entities that provide prescription drug benefits to their active and/or retired employees and their dependents, including public and private employers and unions who participate in Medicare's Retirement Drug Subsidy program ("RDS"), pursuant to which the Government subsidizes a portion of eligible participants' prescription drug costs. Medco clients also include Part D Plan Sponsors, to which the Government makes payments on behalf of Part D beneficiaries.

10. Medco also sponsors its own Part D prescription drug plans ("the Medco PDPs"), contracting with the Government to provide prescription drug benefits directly to Part D

participants, as well as to certain EGWP Sponsors. Additionally, Medco serves as an aggregating PBM, submitting claims on behalf of numerous other PBMs' Part D prescription drug plans.

11. Medco administered services for over 65 million health plan beneficiaries and managed over 40 million prescriptions in 2010 alone.

12. Between December 2003 and October 2006, Medco was involved in civil litigation with the United States in which it was accused of serious, intentional violations of federal law, including hiding rebates which it was contractually obligated to share with its customers, soliciting kickbacks from pharmaceutical manufacturers to favor those manufacturers' drugs, and destroying and canceling valid patient prescriptions.

13. In October 2006, contemporaneous with three settlement agreements with the United States for false claims under the FCA, Medco entered into a CIA with the Office of Inspector General of the Department of Health and Human Services and the Office of Inspector General of the Office of Personnel Management (collectively, "the OIG").

14. During the course of the litigation and settlement negotiations, Medco was aware that the government was particularly concerned about the numerous profit-seeking tactics Medco used to disguise and conceal rebates from pharmaceutical manufacturers to avoid its obligations to pass them on to its customers. It is in this context that Medco entered into the CIA.

15. In pertinent part, under Section II.C.2(a) of the CIA, Medco is required to monitor and track all "focus arrangements," which term is defined as all arrangements under which "compensation or remuneration is received by Medco from or on behalf of a pharmaceutical manufacturer, including but not limited to, rebates, regardless of how categorized, market share

incentives, commissions, fees under products and services agreements, fees received for sales utilization data and administrative or management fees."

16. Importantly, this definition specifically excludes only limited situations involving "purchase discounts based upon invoiced purchase terms."

17. Based on generally-accepted accounting definitions and industry practice, "purchase discounts," are relatively small discounts provided based on the timing or manner of invoice payment, such as discounts for prompt payment or payment in cash. As a result, typical purchase discounts received by a PBM are not normally sought by or directly passed on to the PBM's clients, because such discounts are by definition based solely on the manner in which the PBM pays manufacturer invoices, are unrelated to a PBM's formulary or coverage review activities, and because such discounts are typically very small, *e.g*. less than 2%.

18. "Rebates," on the other hand, are significant price reductions and are customarily based on the dispensed volumes of a manufacturer's product within a PBM's client formularies, *i.e.*, lists of preferred prescription products, (known as formulary, base or access rebates), and may include additional manufacturer payments for increasing a product's market share, (known as incentive or market share rebates), all of which are shared with a majority of a PBM's clients.

19. Upon information and belief, the definitional exclusion requested by Medco for "purchase discounts based on invoiced purchased terms" was understood and intended by the Federal Government to address the customary industry invoice-payment practices described above, and was not intended to exclude more substantial, performance-based discounts which are in substance rebates.

20. Relator became familiar with the "purchase discount" exception language as a part of his CIA compliance training in early 2007.

21. Relator believes that Medco knowingly inserted the purchase discount exclusion into the CIA to allow it to continue the deceptive practice of disguising the rebates it received from manufacturers as purchase discounts. In particular, Medco knew it had existing agreements with AstraZeneca pursuant to which rebate payments were intentionally mischaracterized as purchase discounts.

22. Starting in or about early 2005, Medco engaged in negotiations to revise agreements with AstraZeneca ("AZ") to purchase a number of AstraZeneca drugs, including the blockbuster acid-reflux medication Nexium and high-blood-pressure drug Toprol-XL. However, Relator, who was responsible for tracking rebates, became aware that Medco requested that price reductions be artificially divided between separate agreements. The primary agreements were drawn up as 'typical' rebate agreements for retail and mail-order dispensing (the "AZ Rebate Agreements"), and the secondary agreements, the "discount" agreements, were limited to Medco's mail-order pharmacy purchases of Nexium and Toprol-XL (the "AZ Discount Agreements") (collectively, the "AZ Agreements").

23. The AZ Agreements for Nexium (the "AZ Nexium Agreements") were executed in or about November of 2005, and the AZ Agreements for Toprol-XL (the "AZ Toprol-XL Agreements") were executed in or about January of 2007.

24. The AZ Discount Agreements, both facially and in practice, were not purchase discounts based on invoiced purchase terms, but were rebates based on formulary placement, just like the other rebates provided for in the companion Rebate Agreements.

25. Medco disclosed the AZ Rebate Agreements to the Government under the CIA, and to Medco clients to whom it was contractually obligated to disclose such agreements. However, based on Relator's knowledge of Medco's practices, Medco did not disclose the AZ

Discount Agreements to the Government or to those clients, including its clients that are state run healthcare plans and unions, treating the discounts provided therein as purchase discounts, when they were in fact rebates given in exchange for formulary placement and the lock-out of competing drugs. Relator was aware that Medco tracked purchase discounts internally in many respects as if they were rebates.

26. In or about January 2007, merely three months after signing the CIA, Medco both renewed the AstraZeneca Agreements for Nexium, and executed the AZ Agreements for Toprol-XL.

27. Medco publicly proclaims that it "reduce[s] drug costs for [its] clients primarily through programs that . . . drive competitive discounts from brand-name . . . pharmaceutical manufacturers, including rebates from brand-name pharmaceutical manufacturers." (*See, e.g.,* Medco 2010 Form 10-K Annual Report at 1). In reality, Medco has also been improperly *hiding* significant rebates from its clients.

28. Upon information and belief, Medco received hundreds of millions of dollars in increased profits from the AZ Discount Agreements, which should have otherwise been transparent and made available via customary rebate sharing arrangements to most of Medco's clients, including state and privately funded health plans receiving Government subsidies, Part D Plan Sponsors, state run healthcare plans and unions, and Medco PDP members on behalf of whom the Government makes payments directly to Medco. Indeed, state run healthcare plans and unions specifically contract for transparency and the complete pass-through of rebates.

29. A significant portion of the relevant AstraZeneca mail-order drug purchases are utilized in prescriptions dispensed to retiree beneficiaries enrolled in plans that receive RDS

program subsidies, to Part D beneficiaries enrolled in Part D Plans, and to members of state run healthcare plans and unions.

30. Medco's knowing concealment and failure to disclose the AZ Discount Agreements materially and adversely affected its RDS clients, Part D Plan Sponsor clients, and state run healthcare plan and union clients because they would have been entitled to receive additional formulary rebates for the drugs covered by the AZ Discount Agreements, without taking additional formulary/coverage actions to earn such discounts, and because the undisclosed discounts were significant.

31. Despite its internal anti-fraud training programs required by its CIA and its compliance, fraud, waste and abuse programs that were implemented to comply with the rules for pharmaceutical services companies providing services related to Medicare prescription drug benefits, Medco deliberately concealed the AZ Discount Agreements even though it knew, or should have known, that those discounts would effectively increase RDS and Part D Plan payments, and increase costs paid by state run healthcare plans and unions, and thus defraud the state and federal governments.

32. Medco violated the terms of the CIA, or, at the very least, blatantly subverted its intent, by mischaracterizing the rebates under the AZ Discount Agreements as discounts, rather than rebates, in order to avoid the CIA's tracking, monitoring and reporting requirements.

33. Medco intentionally avoided informing the Federal Government, as well as states, private employers, unions and health plan administrators, of the true price being paid by Medco for the relevant AZ drugs, thus engaging in precisely the same type of deceptive and fraudulent conduct which led to the CIA.

34. Further, and as described more fully herein, Medco violated the federal False Claims Act and state False Claims Acts by engaging in fraudulent and deceptive sales and business practices, soliciting and receiving what amounted to under-the-table kickbacks from AstraZeneca, and knowingly presenting, and/or causing to be presented, to the state and federal governments false claims for payment and/or false certifications material to those payments.

35. This resulted in the Federal Government paying greater RDS subsidies and Part D Plan related payments for the secretly-discounted drugs, and/or reimbursing or subsidizing drugs for which the Government would not have made any payments had it known that the decision making process with respect to the purchase of such drugs was tainted by violations of the Anti-Kickback Statute. These damages to the Federal Government – and the taxpayers – accounted for millions of dollars of damages annually to the Federal fisc.

36. This also resulted in state healthcare plans and unions paying more for pharmacy benefits for the secretly-discounted drugs for which they would not have made any payments had they known of the secret rebates and that the decision making process with respect to the purchase of such drugs was tainted by kickbacks.

III. JURISDICTION AND VENUE

37. Pursuant to 28 U.S.C. § 1331, this Court has jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. § 3729 *et seq*.

38. In addition, the FCA specifically confers jurisdiction upon United States District Courts under 31 U.S.C. § 3732. This court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant is incorporated in Delaware and transacts business in the District of Delaware.

39. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because certain of the acts complained of herein occurred in or affected the District of Delaware.

40. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and Defendant has sufficient minimum contacts with the United States of America.

41. In accordance with 31 U.S.C. § 3730(b)(2), the Second Amended Complaint was filed *in camera* and remained under seal for a period of at least 60 days and was not served on the Defendants until the Court so ordered.

42. Also, in accordance with N.J.S.A. § 2A:32C-5(c), Cal. Gov't. Code § 12652(c)(2), and Fla. Stat. Ann. § 68.083(2)-(3), the Second Amended Complaint was been filed *in camera* and remained under seal for a period of at least 60 days and was not be served on the Defendants until the Court so ordered.

43. Pursuant to 31 U.S.C. § 3730(b)(2), the Relator must provide the Government with a copy of the Complaint and/or a written disclosure of substantially all material evidence and material information in his possession contemporaneous with the filing of the Complaint. Relator has complied with this provision by serving copies of this Third Amended Complaint upon the Honorable Charles M. Oberly, III, United States Attorney for the District of Delaware, and upon the Honorable Loretta E. Lynch, Attorney General of the United States. Relator also previously provided substantially all material evidence and material information in his possession to the Office of the United States Attorney for the District of New Jersey and the District of Delaware. Relator is also serving this Third Amended Complaint on the Attorneys General for the States of California, Florida, and New Jersey. Relator also previously provided

substantially all material evidence and material information in his possession to the Attorneys General for the States of California, Florida, and New Jersey

44. Relator is not aware that the allegations in this Complaint have been publicly disclosed. Further, to the extent Relator is aware of any public disclosures, this Complaint is not based on such public disclosures. In any event, this Court has jurisdiction under 31 U.S.C. § 3730(e)(4) because the Relator is an "original source" because he has provided his information voluntarily to the Government before filing this Complaint, and has knowledge which is both direct and independent of any public disclosures to the extent they may exist.

IV. THE PARTIES

45. Relator, Paul Denis, is a former Vice President of Pharmaceutical Contracting for Medco, where he worked for over 15 years as a high-level employee specializing in pharmaceutical contracting and in that capacity became familiar with all aspects of Medco's pharmaceutical contracting business. Relator received his MBA from the University of Wisconsin in 1982 and he currently resides in Wisconsin.

46. Relator was hired by Medco in 1992 as a Director of Special Drug Purchasing, a title which was later changed to Director of Pharmaceutical Contracting. In 1995, Relator was promoted to Vice President of Pharmaceutical Contracting, a position in which he remained until becoming a Vice President in Employer Sales in 2007.

47. During his tenure at Medco, Relator administered and negotiated contracts with pharmaceutical companies, solicited pharmaceutical company rebates and discounts, managed accounts receivable, and developed contracts for Medicare Part D. In 2005, Relator negotiated the first arms length agreement between Medco and its former parent, Merck & Company ("Merck").

48. Relator left Medco in November 2008. Relator consistently received outstanding performance reviews during his employment, including numerous special recognitions and bonuses.

49. From his employment at Medco, Relator gained direct, personal and independent knowledge of pharmaceutical pricing and discounts, including those described herein.

50. Relator is an original source and has direct, personal and independent knowledge of the information upon which the allegations herein are based.

51. Founded in 1983, and headquartered in Franklin Lakes, NJ, Medco Health Solutions was purchased by pharmaceutical giant Merck & Co. in November 1993, and was operated by Merck as an independent subsidiary until it was spun off as a separate publicly traded company in August 2003.

52. On July 20, 2011, Medco Health Solutions entered into a merger agreement with Express Scripts, Inc. ("ESI"). On April 2, 2012, the merger was completed and ESI and Medco Health Solutions were combined as subsidiaries of a new holding company, Express Scripts Holding Company.

53. Medco Health Solutions provides drug benefit services to approximately 65 million people and is one of the largest PBMs in the United States. Medco Health Solutions' mail-order pharmacy is the industry's largest pharmacy based on the quantity of prescriptions dispensed.

54. In 2010, Medco Health Solutions managed 740 million prescriptions, including 109.8 million prescriptions dispensed through its mail-order pharmacies. Medco Health Solutions' 2010 net revenues were $66 billion, and its net revenues were $70.1 billion in 2011.

55. Headquartered in St. Louis, Missouri, Express Scripts is now the largest PBM company, managing more than a billion prescriptions each year. Express Scripts' 2012 revenue was $93.9 billion dollars.

V. GOVERNING LAWS, REGULATIONS AND CODES OF CONDUCT

A. The Federal False Claims Act

56. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. Further clarifying amendments were adopted in May 2009 and March 2010.

57. The FCA imposes liability upon any person who "knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval"; or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim"; or "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(A), (B), (G). Any person found to have violated these provisions is liable for a civil penalty of up to $11,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

58. Significantly, the FCA imposes liability where the conduct is merely "in reckless disregard of the truth or falsity of the information" and further clarifies that "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b)(1).

59. The FCA also broadly defines a "claim" as one that includes "any request or

demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that – (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government – (i) provides or has provided any portion of the money or property requested or demanded; or (ii) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2)(A).

60. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any Defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene in the action. 31 U.S.C. § 3730(b).

61. The payment or receipt of kickbacks by or from a party which seeks reimbursement from a federal government health program, or causes another party to seek such reimbursement, while certifying or impliedly certifying compliance with the Anti-Kickback Statute, or causing another party to do so, constitutes a violation of the FCA.

B. <u>The State False Claims Acts</u>

62. This action is also filed on behalf of several states with False Claims Acts that closely track the Federal FCA: the California False Claims Act, Cal. Govt. Code §§ 12650, *et seq.*; the Florida False Claims Act, Fla. State. Ann. §§ 68.081, *et seq.*; and the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*

C. Federal Government-Funded Health Assistance Programs

1) Medicare

63. Medicare is a federal government-funded medical assistance program, primarily benefiting the elderly, that was created in 1965 when Congress enacted Title XVIII of the Social Security Act, ("Title XVII"), 42 U.S.C. § 1395 *et seq.* Medicare is administered by the federal Centers for Medicare and Medicaid Services ("CMS"), which is a division of the U.S. Department of Health and Human Services ("HHS"). Since 2006, Medicare Part D has provided optional prescription-drug coverage to persons eligible for Medicare coverage.

64. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amendment to Title XVIII created the Part D Voluntary Prescription Drug Benefit Program which, as of January 1, 2006, added certain prescription drug benefits, covered by Part D prescription drug plans and employment-based "qualified retiree prescription drug plans," to the benefits covered under Medicare. *See* 42 U.S.C. §§ 1395w-101, 1395w-132; 42 C.F.R. § 423.882.

65. Under the MMA, eligible Medicare Part D beneficiaries can obtain prescription drug coverage through private Part D prescription drug plans. Potential Part D Plan Sponsors, including Medco and other PBMs, submit bids annually to CMS in order to participate in the Part D program. 42 C.F.R. § 423.265. CMS reviews and approves these bids, and Part D Plan Sponsors then enter into direct contracts with CMS to provide drug benefits to Part D participants.

66. CMS makes prospective payments to Part D Plan Sponsors based on estimated costs. These include monthly direct subsidy premium payments for each Part D enrollee based on the plan's approved bid amount, reinsurance payments for eighty percent (80%) of the Plan Sponsor's costs for catastrophic coverage for Part D enrollee's above a certain threshold, and

low-income subsidy ("LIS") payments for premium and cost-sharing charges for low income individuals. Part D Plans, in turn, provide CMS with documentation of their actual costs.

67. Following the close of the benefit year, CMS reconciles a Part D Plan Sponsor's actual incurred prescription drug costs against the Plan Sponsor's bid. If the Plan Sponsor's actual costs exceed estimated costs, the Sponsor may be able to recoup some of its costs through a risk-sharing arrangement with CMS. If a Part D Plan Sponsor's estimated costs exceed its actual costs, the Sponsor may have to pay back some of the payments made to it by CMS.

68. Part D Plan Sponsors are required to make a number of significant and material certifications to CMS regarding the submission of data used for payment. *See e.g.*, 42 C.F.R. § 423.505(k) *et seq.*

69. Notably, all "direct or indirect remuneration" from pharmaceutical manufacturers, regardless of whether the remuneration is properly retained by the PBMs, or is passed-through to their clients, is specifically excluded from coverage under the regulations for Part D Plan Sponsors. § 423.308 *et. seq.*

70. Through the MMA's Retiree Drug Subsidy program, CMS contracts with employers or unions offering "qualified retiree prescription drug coverage" to their Medicare-eligible retirees ("RDS Plan Sponsors"), and provides a subsidy for a portion of their retiree drug costs between specified levels.

71. The RDS subsidy can be claimed for each person enrolled in the employer's plan who would otherwise be enrolled in Medicare Part D. The subsidy is equal to 28% of "allowable retiree costs," meaning the part of prescription drug costs that are actually paid by the employer or the retiree, net of any discounts, rebates or similar price concessions. 42 U.S.C. § 1395w–132.

72. Potential RDS Plan Sponsors must submit an application for each year in which

they plan to request a subsidy. Plan Sponsors elect a payment frequency during the application process, and may make as many as twelve interim payment requests per plan year. 42 CFR § 423.888(b)(1). RDS Plan Sponsors or their representatives, such as PBMs acting on their behalf, must submit cost data to CMS' RDS Center before submitting any interim payment requests. Those plans which have elected to only receive payments annually must submit cost data at the time of reconciliation. 42 CFR § 423.888(b)(2).

73. Following the close of the benefit year, CMS reviews the total gross covered retiree prescription drug costs and actual cost adjustments, such as those related to manufacturer price concessions, submitted by the RDS Plan Sponsor after the plan year has ended, and makes a final subsidy payment determination. 42 CFR § 423.888(b)(4). CMS then reconciles the sum of any payments made to the RDS Plan Sponsor with its final subsidy payment determination, and if the sum of the interim payments made is larger than the final subsidy payment determination, will initiate an overpayment recovery action.

74. In order to receive a subsidy payment, RDS Plan Sponsors must specifically accept and agree to certain terms, including acknowledging, and requiring all subcontractors to acknowledge, that information being provided in connection with the RDS application or subcontract, is being used for the purpose of obtaining federal funds. *See e.g.*, 42 C.F.R. 423.884(c)(3).

2) <u>Medicaid</u>

75. The Medicaid program was created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to cover the medically needy aged, the blind, the disabled, and needy families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both federal and state monies, (collectively

referred to as "Medicaid Funds"), with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b). At the federal level, Medicaid is administered by CMS. Medicaid is used by 49 states, each of which has a state Medicaid agency to administer the program.

76. Each state is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the HHS. Among other forms of medical assistance, the states are permitted to provide medical assistance from the Medicaid Funds to eligible persons for inpatient and outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(12).

77. Federal law prescribes that drug manufacturers must pay rebates to the states to insure that the Medicaid Rebate Program is paying the lowest price the manufacturer sells a covered outpatient drug to any purchaser in the United States, inclusive of cash discounts, free goods, kickbacks, volume discounts and rebates. The best price provision is intended to ensure that the government is being provided the lowest price on drugs.

D. Applicable Provisions

1) The Anti-Kickback Statute

78. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, renders it impermissible for anyone to solicit or receive kickbacks related to goods or services for which payment may be made, in whole or in part, pursuant to a Federal health care program.

79. The Anti-Kickback Statute defines "illegal remuneration" (*i.e.*, kickbacks) as:

> (1) whoever knowingly and willfully *solicits or receives* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
>
> * * *
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be

> made in whole or in part under a Federal health care program,
>
> * * *
>
> (2) whoever knowingly and willfully *offers or pays* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> * * *
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

42 U.S.C. § 1320a-7b(b) (emphasis added). The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to five years. 42 U.S.C. § 1320a-7b(b).

80. The Anti-Kickback Statute contains statutory exceptions and regulatory "safe harbors" excluding certain types of conduct from liability. See 42 U.S.C. § 1320a-7b(b)(3) and 42 C.F.R. § 1001.952. None of these statutory exceptions or regulatory safe harbors applies to Defendants' conduct in this matter.

81. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 imposed administrative civil monetary penalties for Anti-Kickback Statute violations: $50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

82. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law

as a condition of payment under, and participation in, Government healthcare programs.

2) Prohibitions Against Claims for Services that are Not Medically Necessary or are Otherwise False or Fraudulent

83. Federal law prohibits a person from knowingly presenting or causing to be presented to Medicare or Medicaid a claim for a medical or other item or service that the person knows or should know was "not provided as claimed," a claim for such items or services that is "false or fraudulent," or a claim that is "for a pattern of medical or other items or services that [the] person knows or should know are not medically necessary." 42 U.S.C. §§ 1320a-7a(a)(1)(A), (B) & (E). Violation of this section is subject to a civil monetary penalty of $10,000 for each item or service, plus damages measured as three times the amount of each claim submitted, and exclusion from further participation in the programs.

E. State Government-funded Healthcare Plans

1) California

84. In California, for example, the California Public Employees' Retirement System (CalPERS) manages pension and health benefits for California public employees, retirees and their families. Medco managed the pharmacy benefits for CalPERS members from 2006 through 2011, when CalPERS decided not to renew Medco's contract based on evidence of misconduct related to Medco's solicitation of its original contract with CalPERS.

2) Florida

85. In Florida, for example, Florida's State Group Insurance Program provides health benefits for salaried employees, eligible dependents and retirees. Express Scripts/Medco is the pharmacy benefits manager for the State Group health insurance plans (except the CHP Retiree Advantage plan and the FHCP Medicare Advantage plan).

3) New Jersey

86. In New Jersey, for example, the New Jersey State Health Benefits Program (SHBP) and The School Employees' Health Benefits Program (SEHBP) offer medical and prescription drug coverage to qualified public employees, retirees, and eligible dependents. The prescription drug plans of the SHBP and SEHBP are administered by Medco/Express Scripts.

VI. SPECIFIC ALLEGATIONS

A. Medco and the Pharmacy Benefit Management Business

87. One of the most significant trends in the health care industry in the late 1980s and early 1990s was the rise of Pharmacy Benefit Managers.

88. In the 1980s, PBMs and their precursors provided mail order pharmacy services and prescription claims processing for employers. In the early 1990s, with the growth of Health Maintenance Organizations (HMOs), PBMs' power and influence in the health care industry increased exponentially. HMOs, seeking to create efficiencies of scale and save healthcare dollars by establishing drug formularies, partnered with PBMs to obtain discounts on medications from drug manufacturers due to the volume and market share that inclusion on formularies could drive. These arrangements also encouraged (or required) doctors to prescribe and pharmacists to fill favored medications for HMO patients.

89. During the 1990s, several large pharmaceutical companies acquired PBMs in an effort to increase their market share by controlling the drugs to be included on (and excluded from) PBM formularies and promoted by PBMs to pharmacists and prescribing physicians. However, after regulators required that PBM formulary decisions remain independent of their parent drug companies, many manufacturers divested their PBMs.

90. Beginning in January 2006, with the establishment of the new Part D Voluntary

Prescription Drug Benefit Program, PBMs were able to extend their business to the Medicare population. Under the Part D program, beneficiaries have the option of joining Part D prescription drug plans which pay for those beneficiaries' pharmaceuticals and which, in turn, get reimbursed by Medicare. Many of these plans use PBMs to obtain medications and set drug formularies.

91. In addition, through the RDS program, Medicare eligible retirees can remain in state or private employer-sponsored drug plans which receive federal subsidies under Part D, as an alternative to participating in a Part D prescription drug plan. These employer-sponsored drug plans also use PBMs to obtain medications and set drug formularies. Upon information and belief, a significant portion of Medco's AstraZeneca mail-order drug purchases involve retiree beneficiaries enrolled in plans receiving RDS program subsidies.

92. PBMs have also been able to extend their business to the Medicare population by contracting directly with CMS to themselves serve as Part D Plan Sponsors, providing pharmacy benefits directly to Medicare beneficiaries and to EGWP Sponsors which have elected to purchase their EGWPs from a PBM.

93. In January 2006, the three largest independent PBMs, Medco Health Solutions, Caremark, and ESI, were processing prescription benefits for over 150 million people and generating combined revenues of $89 billion. In 2010, over 350 million Americans nationwide received drug benefits administered by PBMs, with the three largest representing well over 200 million lives. Today Express Scripts Holding Company covers approximately 137 million lives, and commands over a third of the market.

94. Over the past several years, PBMs have come under increased scrutiny and have been the subject of lawsuits by federal and state governments, health plans, employers, unions

and individuals for, among other things, failing to disclose secret discounts to clients, manipulating formularies to favor drug companies who offer them kickbacks, recommending drug coverage exclusions that benefited the sales of higher margin drugs, and improperly switching patients' prescriptions from those originally prescribed by their physicians to drugs manufactured by companies from which the PBMs were receiving payments, regardless of whether or not those drugs were most appropriate for the patients, or were even the most cost effective for their insurers.

B. Medco's Fraudulent Actions

1) The Corporate Integrity Agreement and Rebate Agreements

95. Between December 2003 and October 2006, Medco was involved in civil litigation with the United States in which it was accused of serious, intentional violations of federal law, including hiding rebates which it was contractually obligated to share with its customers, soliciting kickbacks from pharmaceutical manufacturers to favor those manufacturers' drugs, and destroying and canceling valid patient prescriptions.

96. In October 2006, Medco entered into a CIA with the OIG. The CIA was contemporaneous with three settlement agreements with the United States for claims under the FCA involving, among other claims, improper payment received from drug manufacturers to favor those manufacturer's products.

97. Pursuant to Section II.C.2(a) of the CIA, Medco is required to monitor and track all "focus arrangements," which term is defined as all arrangements under which "compensation or remuneration is received by Medco from or on behalf of a pharmaceutical manufacturer, including but not limited to, rebates, regardless of how categorized, market share incentives, commissions, fees under products and services agreements, fees received for sales utilization

data and administrative or management fees."

98. Importantly, the CIA specifically excludes from this definition "purchase discounts based upon invoiced purchase terms."

99. The term "arrangements" is defined as "every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value: and is between Medco and any actual or potential source of health care business or referrals to Medco or any actual or potential source of health care business or referrals from Medco;" and "health care business or referrals" is to be read to "include referring, recommending, arranging for, ordering, leasing or purchasing of any good, facility, item or service for which payment may be made in whole or in part by a federal health care program."

100. The CIA imposes penalties for failing to comply with the reporting and other provisions of the agreement and includes a provision providing for the exclusion of Medco from participation in Federal health care programs for a material breach of the CIA.

101. Under the CIA, the OIG has the right to audit Medco and to interview Medco's employees or contractors for the purposes of verifying and evaluating Medco's compliance with the terms of the CIA, and with the requirements of Medicare, Medicaid, and other Federal health care programs.

2) <u>The AstraZeneca Agreements</u>

102. AstraZeneca PLC is a British-Swedish pharmaceutical company headquartered in London, formed by the 1999 merger of Swedish pharmaceutical company Astra AB and the United Kingdom's Zeneca Group PLC. AstraZeneca's United States subsidiaries include AstraZeneca Pharmaceuticals, L.P., located in Delaware, and AstraZeneca L.P., headquartered in Pennsylvania.

103. AstraZeneca's most successful medication has been omeprazole, a proton pump inhibitor ("PPI") used in the treatment of ulcers and gastroesophageal reflux disease. Originally marketed under the brand name Prilosec, the medication was a "blockbuster," achieving annual sales of approximately $6 billion.

104. However, Prilosec's patent was due to expire in 2002, so AstraZeneca sought to maintain its dominance of the PPI market with the introduction of the chemical compound esomeprazole, which it began marketing under the brand name Nexium. Nexium was essentially the same medication as Prilosec, but esomeprazole contains one of two mirror-image molecules which combined to form a single molecule in Prilosec, so Nexium was patentable as a separate medication.

105. Nexium was heavily marketed by AstraZeneca as a newer and better version of Prilosec in one of the most expensive marketing campaigns in history. In 2003, AstraZeneca spent $260 million promoting Nexium to American consumers, by far the highest consumer marketing budget for any drug at the time.

106. This relentless promoting of Nexium skyrocketed United States sales of Nexium to $2.7 billion in 2004. By 2006, Nexium had more than $5 billion in global sales, and was the second best selling drug in the world, with more than seven million Americans being prescribed the medication.

107. In August 2003, pharmaceutical giant Merck spun off Medco as a separate corporation. In its numerous post-Merck public disclosures, Medco senior executives acknowledged that Medco was contractually required to pass on a large percentage (approximately 80% to 90%) of manufacturer rebates to its clients.

108. During this period, Relator heard one of Medco's senior executives specifically

complain that rebates were not generating enough revenue, and stated that his team needed to get creative about earning additional money for Medco.

109. Beginning in or about 2005, in order to incentivize Medco to push its top drugs Nexium and beta-blocker, Toprol-XL, and to place those drugs on formularies, Medco persuaded AstraZeneca to enter into a series of agreements which contained secret kickbacks and were designed to conceal these incentives from Medco clients and the government.

110. Just months before signing the AstraZeneca Agreements, Medco lost a $100 million plus per year contract with Wyeth (now a part of Pfizer) for its proton pump inhibitor Protonix. Shortly thereafter, Medco contacted AstraZeneca seeking to construct a deal for Nexium that would compensate for the huge loss in earnings Medco would experience from the loss of the Wyeth contract.

3) At Medco's Request AstraZeneca Agreed to Conceal Rebates in Secret Agreements

111. While at Medco, Relator learned that AstraZeneca had approached Medco in early 2005, and offered to substantially increase rebates to Medco in order to obtain formulary exclusivity in Medco prescription drug plans. Medco's response to AstraZeneca was to offer not only formulary exclusivity, but the complete lock out of competitor drugs from Medco drug plans, on the condition that AstraZeneca re-characterize a portion of the offered rebates as discounts, which would be treated as purchase discounts, appearing only on the invoice, and reducing the price to Medco, but not to the client. The AZ Agreements contained such "lock-out provisions." These agreements were designed to create additional profit for Medco that would be concealed from its customers.

112. The discount contracts and the rebate contracts were negotiated at the same time and as part of the same agreements. Relator knows of no legitimate business purpose for creating

separate agreements for the discount provisions. Relator is aware, however, that Medco had a practice of creating separate agreements for the purpose of removing those agreements and the flow of money under those agreements from the audit stream and concealing those agreements from clients, including the Government.

113. Upon information and belief, Medco had not previously entered into separate or side agreements with branded pharmaceutical manufacturers regarding discounts, and in any event such agreements had not previously been commonly part of Medco's major branded drug acquisition contractual arrangements. Specifically, The AZ Nexium Agreements were executed in or about November of 2005. The discount agreement for Nexium (the "Nexium Discount Agreement") provided Medco with a "NEXIUM DISCOUNT" of the Wholesale Acquisition Cost ("WAC") of the drug minus ten percent (10%).

114. The AZ Toprol-XL Agreements were executed in or about January of 2007. The discount agreement for Toprol-XL (the "Toprol-XL Discount Agreement") provided Medco with a "TOPROL-XL DISCOUNT" of WAC minus thirty percent (30%).

115. Concurrently with the AZ Agreements, Medco made Nexium its exclusive branded proton pump inhibitor in its national formulary, Preferred Prescriptions. Medco granted similar formulary exclusivity to Toprol-XL.

116. Significantly, in exchange for the increased rebates it obtained pursuant to the AZ Discount Agreements, Medco also agreed to the complete lock-out from its drug plans of drugs which compete with Nexium and Toprol-XL.

117. Relator has personal knowledge that, following the signing of the AZ Agreements, Medco aggressively pushed its relationship with AstraZeneca and moved Nexium to the top of its formularies. Nexium became the number one purchased drug in Medco's

business.

118. The Relator has personal knowledge that the AZ Discount Agreements generated an unusual degree of excitement and self-congratulations on the part of the Medco Pharmaceutical Contracting Group and others, and yet, oddly, was not widely discussed even within the group that handled such contracts, but rather was kept largely under wraps.

119. Since new, retained purchase discounts would significantly and materially enhance Medco's gross profits and his personal recognition, Relator believes that Nardin informed Medco's CEO and CFO of this scheme's financial benefits (Nardin reported directly to the CEO). In addition, Medco's Employer Customer Group's president Bryan Birch informed Relator that Nardin, through Medco's Executive Committee, had a significant portion of the year-end 2006 and 2007 executive bonuses in Medco's customer groups tied to the success of Formulary Coverage Review ("FCR"), a program Mr. Nardin managed and a critical element of Nexium's post-Nexium Discount Agreement promotion. Also in late 2007, Relator and Bryan Birch had face-to-face meeting with John Henderson and Tom Moriarty (other executives in charge of Medco's pharmaceutical contracting) regarding the recent renewal of the Nexium Discount Agreement. As a result of that meeting, Relator believed Henderson and Moriarty were aware of the financial benefits of the Nexium Discount Agreement scheme.

120. In or about January 2007, Medco and AstraZeneca renewed the AZ Nexium Agreements and executed the AZ Toprol-XL Agreements. The substance of the agreements, and the unusual bifurcated structure, remained intact, despite Medco's having entered into the CIA just 3 months earlier, which was aimed directly at transparency of all rebates and preventing future violations of federal law and of regulations relating to federal health care programs such as Medicare.

121. Customary pharmaceutical manufacturer purchase discount incentives generally provide for two percent discounts off the Wholesale Acquisition Cost ("WAC') of all of a manufacturer's drugs sold pursuant to a given invoice if that invoice is paid promptly, including those purchased directly by a PBM for its own mail-order pharmacy's use. For example, a typical purchase discount agreement follows a "2/10 net 30" formula, under which the purchaser receives a two percent discount for paying an invoice within 10 days of the invoice date.

122. Contrary to this customary industry practice, the AZ Discount Agreements provided incentives far greater than a two percent discount, and these incentives were not tied to prompt payment, but instead were tied to volume, just as formulary rebates are.

123. Upon information and belief, the AstraZeneca Agreements contained separate provisions which paid Medco 2% for the prompt payment of invoices. By contrast, the "NEXIUM DISCOUNT" and "TOPROL-XL DISCOUNT" language in the agreements did not require any specific time of payment and did not require prompt payment or any specific manner of payment; merely by paying for Nexium and Toprol-XL, Medco received the discounts.

124. Although they attempted to maintain the fiction that the discounts Medco was receiving were different than the rebates, Medco and AstraZeneca treated these discounts and rebates as interchangeable. The fact that Medco and AstraZeneca viewed these purchase discounts and rebates as interchangeable was confirmed when, in 2007, Medco renewed its Nexium contract with AstraZeneca, and AstraZeneca requested that Medco "move" some of the rebates it was receiving in the form of the NEXIUM DISCOUNT over to the client rebate category in order to better incentivize Medco clients to make Nexium exclusive on their formularies, and/or to lock out other competitors, and Medco agreed.

125. Relator met with Mr. Jeff May, a senior executive at Medco, around this time, and

reviewed the renewal agreements and discussed them. During this time, Relator was told that AstraZeneca had complained to Medco that the rebates being passed through to the client were not large enough to incentivize the client to make Nexium exclusive on its formulary, and/or to lock out other competitors. AstraZeneca requested that Medco "move" some of the rebates it was receiving in the form of purchase discounts over to the client rebate category and Medco agreed. Thus, there was a direct, inverse relationship between purchase discounts and rebates. Both AstraZeneca and Medco agreed that the purchase discounts and rebates were two sides of the same coin, and treated them as such.

126. Relator also reviewed the AZ Agreements shortly after they were executed and learned that, as an additional incentive to obtain the discounts, Medco took the highly unusual step of agreeing to forfeit potential audit rights with respect to past rebate agreements with AstraZeneca.

127. Medco's plainly artificial and intentional segregation of the AstraZeneca rebates into separate "rebate" and "discount" agreements was a sham to disguise and conceal a portion of Medco's financial incentives and thus avoid having to disclose (and share) these rebates with its clients. Treating what in substance was a rebate as a purchase discount, likewise served to circumvent the CIA's reporting requirements while appearing fully transparent and in compliance with the CIA.

128. For example, upon information and belief, when clients requested information about the net cost of their drugs after rebates to confirm that they were getting rebate pass-throughs, the reports they were given did not reveal the existence of the NEXIUM and TOPROL-XL DISCOUNTS, and the discount figures were not included in the net cost analysis prepared for them. Therefore, when a client was making a decision whether or not to prefer

Nexium and/or lock-out Nexium's competitors in its formulary, it could and did not know that Medco was receiving secret kickbacks in the form of purchase discounts if they did so.

129. Medco employees, including Relator, who provided back-up documentation to auditors, including auditors working for clients with manufacturer discount-sharing agreements, were instructed to only include contracts containing provisions for rebates that were passed through to the clients, and not to provide other contracts that related to monies Medco retained. Relator had a conversation with Ms. Regina Dennis, a Vice President at Medco responsible for providing auditors, including those of clients with manufacturer discount-sharing agreements, with backup documentation, in which Relator confirmed that Ms. Dennis followed the same procedure as Relator had been instructed to follow, which was to only provide auditors with contracts containing provisions for rebates that were passed through to the clients, and not to provide other contracts that related to monies Medco retained.

130. Medco's Pharmaceutical Contracting executives also sought to convert rebates into discounts to create private kickback streams as part of negotiations with pharmaceutical manufacturers other than AstraZeneca.

131. Shortly after the initial execution of AZ's Nexium Discount Agreement, Relator and Nardin were co-managing the renegotiation of Merck's rebate deal with Medco. At the time, the Merck deal was Medco's most important rebate negotiation and included frequent briefings to Medco's CEO and its Executive Committee.

132. In a face-to-face meeting in late 2005, Nardin told Relator that he wanted to try a new idea and apply the tactics in Medco's recently signed Nexium deal to Merck – specifically to reduce mail rebates for a commensurate large mail purchase discount. At the time, Relator assumed Medco's policy was transparency and as a result, a bifurcation of Medco's mail rebates

into rebates and discounts was meaningless to its gross profit and to its clients' net drug spend.

133. Nardin requested that a short presentation be prepared with his new proposal for Medco's upcoming meeting with Merck. Also attending the Merck meeting with Relator and Nardin was Joanne Taylor, a Director in Medco's Pharmaceutical Contracting group. The arrangement was proposed to four Merck representatives, including Mr. Andrew Tedeschi, Mr. John Harrington, Mr. Richard Patrylak and Ms. Deborah Gan, by the head of Medco's Pharmaceutical Contracting, Art Nardin. Several days later, Merck responded that it was uncomfortable with this proposal and refused to participate.

134. As Relator recalls, the meeting and the negotiations related to the new purchase discount proposal. Relator also recalls that Merck was confused by Medco's new purchase discount proposal which required them to divide payments into rebates and purchase discounts, and asked Nardin why they should prefer it to the rebates-only structure they had in their existing Medco agreement. In his reply, Nardin asked if Merck was aware of Medco's new efforts to promote Nexium exclusively in formularies and to reduce utilization of Nexium's competitors via Medco's FCR program. Merck confirmed they had heard rumors of Medco's new promotional efforts. Nardin indicated that Nexium's new promotion results within Medco were spectacular and that AZ's new deal structure permitted him the "flexibility" to promote Nexium. Nardin said that if he had a similar purchase discount-type deal with Merck, Medco would have the flexibility to undertake the same kinds of promotions for Merck's leading products.

135. From these discussions, Relator understood that Medco likely intended to retain most of the side deal "purchase discounts" as profit for Medco. However, shortly thereafter Merck declined to pursue the proposed bifurcation because they said they preferred the simplicity of the "rebates-only" deal structure both parties already had in-place and which was

ultimately reused in the new Merck-Medco deal concluded in February 2006.

136. Relator further recalls that in subsequent negotiations Merck asked to participate in Medco's FCR program as a condition to their new rebate deal. Medco and Nardin denied Merck's request and reminded Merck that FCR was the quid pro quo for the purchase discount proposal they had previously rejected.

137. Relator has personal knowledge that not only were Mr. Nardin and other senior executives who worked with him aware of the discounts scheme, but those who succeeded Mr. Nardin, including General Counsel and head of Pharmaceutical Contracting, Thomas Moriarty, were also aware of it. Specifically, Relator presented an analysis he had performed to Mr. Moriarty, in which Relator had determined that it was potentially in the best interests of General Electric to exclude Nexium on its formulary. Relator explained to Mr. Moriarty that it was also in Medco's interest to make this change because of the large subsidies Medco was providing to General Electric on the costs of Nexium. During this conversation, Relator specifically recalls making Mr. Moriarty aware that the Relator had, in his analysis, taken into account the value to Medco of Nexium's secret purchase discounts. Mr. Moriarity and Medco ultimately decided to continue to recommend Nexium to GE as the exclusive covered medication in its relevant formulary therapeutic category.

138. Characterizing an additional rebate on selected AZ products as a discount made it possible for Medco to significantly increase its profits and retain potential drug savings from clients which had bargained to receive a share of any financial inducements obtained on their branded pharmaceutical dispensing. Although some, though not all, of the AZ Agreements contain language to suggest that the discounts will not be provided on Government related programs, Relator has personal knowledge that neither the computerized accounting systems

within Medco, nor the mail-order systems by which Medco dispenses drugs, were set up to segregate, or to make distinctions between, drugs being utilized for Government and for commercial plans, and that Medco did not, in fact, make such distinctions.

139. Based on Relator's knowledge of Medco's computer accounting system and of the people who handled accounting processes both during and after his tenure at Medco, there was, thus, no way for Medco to account for, or to report, these discounts for the purposes of RDS or Part D reporting, either on those reports provided by Medco to participants or on those reports provided directly to the Government by Medco on behalf of participants.

140. Accordingly, such self-serving and illusory provisions were impractical, not enforceable, and designed merely to shield the parties from accusations of wrong-doing in the event the discount arrangements were to come to light. In fact, Relator is informed and believes, that later contracts between the parties even contained acknowledgments that Medco could not, in fact, make such distinctions.

4) Medco's Actions Constitute Violations of the Anti-Kickback Statute and the False Claims Act

141. As detailed above, AstraZeneca clandestinely paid rebates as kickbacks to Medco, which were disguised as purchase discounts to avoid detection. Medco sought these kickbacks, and AstraZeneca paid them, in exchange for Medco favoring certain AstraZeneca drugs on its formularies. The characterization of these discounts as off-invoice discounts was an intentional ploy to circumvent the CIA's reporting requirements while appearing fully transparent. This ploy also facilitated Medco's scheme to retain these rebates and avoid having to report these rebates to its clients. As a result, these rebates were not passed on to Medco's clients or the U.S. Government.

142. The AZ Discount Agreements on NEXIUM and TOPROL-XL unquestionably

violated the intent of the CIA, in that they are nothing more than a form of rebate that should be passed on to Medco's clients, including the U.S. Government, the states (including their employee retirement systems), and private clients applying for drug reimbursements and subsidies under Medicare Part D, including RDS.

143. In addition, putting aside whether its clients were entitled to the rebates (which most of them were), Medco did not disclose to its clients it was receiving these rebates. Indeed, Medco's typical agreements with its clients led clients to believe that Medco was only withholding minor off-invoice discounts based on payment terms and not formulary placement rebates.

144. In fact, Medco specifically solicited these clandestine AstraZeneca rebates in exchange for the placement of Nexium and Toprol-XL on client formularies, with the intent of tainting the decision making process with respect to formulary placement, lock-out of competitor drugs and, ultimately, the purchase of drugs for which reimbursement and subsidy payments would be made by the Government, in violation of the Anti-Kickback Statute.

145. The AZ Discount Agreements also represent clandestine profit sources, or kickbacks, to incentivize Medco to promote the drugs through formulary copay incentives, various patient/prescriber communications, and coverage limitation efforts designed to coerce physicians into prescribing Nexium and Toprol-XL for client patients, including those whose drugs are subsidized or reimbursed by the Government, in violation of the Anti-Kickback Statute and thereby violating the False Claims Act.

146. Further, Medco knowingly submitted and/or caused to be submitted, false certifications (both express and implied) to the Government concerning compliance with the Anti-Kickback Statute, actual compliance with which is a condition of payment by the

Government, in violation of the False Claims Act.

147. These kickbacks were material to Government's payment decision because the Government has a stated policy that it will not pay for services or goods tainted by kickbacks.

5) Medco's Actions Submitted in connection with Part D Violated the FCA

148. Medco's violation of the Anti-Kickback Statute was not only a substantial factor, it was the factor in bringing about the filing of factually false claims and false certifications to the Government on the part of, or on behalf of, plan sponsors.

149. In addition, as set forth in greater detail above, under Part D, Plan Sponsors are required to report all "direct or indirect remuneration" from pharmaceutical manufacturers even if it is retained by the PBM. Medco knowingly submitted false records or statements to clients and to the Government, on behalf of clients, about the cost of drugs, which did not reflect the true cost of those drugs, causing RDS and Part D Plan Sponsors and/or their agents, to submit false reimbursement claims to the Government, in violation of the False Claims Act.

6) Medco's Actions In Connection With the RDS Program Violated the FCA

150. Medco's failure to report and to pass on its hidden rebates to its RDS Sponsor clients, which it was required to do in the majority of cases, caused these clients to submit reimbursement claims to the Government that contained material omissions and did not reflect the total sum of the rebates which were rightfully to have been applied to the drugs they purchased, causing the Government to overpay on RDS reimbursements for those drugs.

151. Medco was not only extremely familiar with the RDS program, but held itself out as an expert on the program, and knew well that its actions would result in substantial overpayments by the Government.

152. Irrespective of whether RDS Sponsors are required to report reimbursements that are not passed through to them, Medco's mischaracterization of the rebates as discounts caused false claims to be submitted by, or on behalf of, Medco's RDS Sponsor clients. These statements were material to the false claims because if the Government had known that it was overreimbursing RDS Sponsors as a result of Medco's fraud it would not have done so.

7) Medco's Actions Constitute Violations of the State False Claims Acts

153. State run healthcare plans, employee retirement systems, and unions, in California, Florida, and New Jersey, contract with and utilize the pharmacy benefits provided by Medco and Express Scripts. They all contract for full disclosure and transparency in pharmacy pricing and require that 100 percent of manufacturer rebates be passed through to the state clients.

154. As detailed herein, Medco sought and obtained secret kickbacks from AstraZeneca, which were disguised as purchase discounts to avoid detection and avoid the requirement of passing through rebates, in exchange for Medco favoring certain AstraZeneca drugs on its formularies. The characterization of these discounts as off-invoice discounts, as opposed to the rebates that they were, was an intentional ploy to appear fully transparent while retaining these rebates and avoiding having to report these rebates to its clients. As a result, these rebates were not passed on to Medco's state clients.

155. The AZ Discount Agreements on NEXIUM and TOPROL-XL unquestionably violated, and no doubt continue to violate, the express terms of these contracts. These purchase discounts are nothing more than a form of rebate that should be passed on to Medco's clients.

156. In addition, aside from the fact that its state clients were contractually entitled to the rebates, Medco did not disclose to them that it was receiving these rebates. Indeed, Medco's

typical agreements with its clients led clients to believe that Medco was only withholding minor off-invoice discounts based on payment terms and not formulary placement rebates. In fact, formulary rebates are rebates that are expected to be passed through to these clients.

157. In fact, Medco specifically solicited these clandestine AstraZeneca rebates in exchange for the placement of Nexium and Toprol-XL on client formularies, with the intent of tainting the decision making process with respect to formulary placement, the lock-out of competitor drugs and, ultimately, the purchase of drugs for which state clients would ultimately be forced to pay a higher price.

158. The AZ Discount Agreements also represent clandestine profit sources, or kickbacks, to incentivize Defendants to promote the drugs through formulary copay incentives, various patient/prescriber communications, and coverage limitation efforts designed to coerce physicians into prescribing Nexium and Toprol-XL for client patients, including those whose drugs are subsidized or reimbursed by the state clients, thereby violating the False Claims Acts.

159. Further, Medco knowingly submitted and/or caused to be submitted, false certifications (both express and implied) to the state clients concerning compliance with state laws, actual compliance with which is a condition of payment, in violation of the state False Claims Acts.

160. These kickbacks were material to the payment decisions by the state clients because they all have stated policies that they will not pay for services or goods tainted by kickbacks.

C. Damages Caused by Medco's Unlawful Scheme

161. As described herein, Medco violated the federal and state False Claims Acts by engaging in fraudulent business practices which resulted in the federal and state governments

overpaying for drugs or over-reimbursing prescription subsidies, and paying for drugs which might not have been prescribed but for the payment of kickbacks by their manufacturer.

162. In mischaracterizing rebates as discounts, and treating them as purchase discounts based on invoiced purchase terms, and thus failing to pass on those "discounts" to its clients eligible for manufacturer rebate-sharing, including RDS Plan Sponsors, Part D beneficiaries enrolled directly in Medco PDPs, employers who obtain their EGWP's from Medco, state run healthcare plans and unions, and other Part D Plan Sponsors whose plans are administered by Medco and, subsequently, Express Scripts, Defendants violated applicable statutes and regulations, including, but not limited to, the Anti-Kickback Statute and the state and federal False Claims Acts.

163. More specifically, because the RDS Program has provided enrolled employers and unions with subsidies for their Part D eligible retirees' prescription drug costs, and has excluded the subsidies received from taxable income, the Federal Government has made substantially higher payments to RDS Plan Sponsors because of Medco's concealment and failure to pass on the rebates it is receiving on covered drugs from AZ.

164. In addition, through direct contracts with state run healthcare plans and unions, and state and privately funded health plans receiving Government subsidies, Medco has received millions of dollars in increased profits from the AZ Discount Agreements, which should have otherwise been transparent and made available via rebate sharing arrangements to these clients.

165. Further, because CMS makes payments to Medco, and to Part D Plans managed by Medco, on behalf of Medicare Part D beneficiaries, Medco's concealment of these rebates is increasing Government payments under the Part D program.

166. Because of Medco's fraudulent practices, state run healthcare plan and union, Part

D Plan and RDS plan participants more frequently purchased, and paid more for, Nexium and Toprol-XL than they would have otherwise, in violation of state and federal law.

167. Medco's illegal actions also caused Medco PDP participants, on behalf of whom CMS makes payments directly to Medco, to overpay for prescription drugs.

168. Medco's illegal actions resulted in a direct annual loss of tens of millions of dollars, and at least $50 million during the relevant period, to the federal and state governments under the False Claims Acts.

VII. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(Violations of Anti-Kickback Statute and False Claims Act)
(42 U.S.C. § 1320a-7a)

169. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

170. By engaging in the conduct described in the foregoing Paragraphs, the Defendants have violated 42 U.S.C. § 1320a-7a and 42 C.F.R. § 1001.952(f).

171. In particular, the Defendants have knowingly caused to be submitted claims to the United States Government as a result of the solicitation and receipt of the above-described kickbacks. The payment or receipt of kickbacks to induce purchases constitutes remuneration to increase the level of business in violation of the anti-kickback statute.

172. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for drugs which, had the Government known were utilized as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

SECOND CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A))

173. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

174. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A).

THIRD CAUSE OF ACTION

(False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B))

175. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

176. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have knowingly made, used, or caused to be made or used, false records or statements – i.e., the false certifications and representations made or caused to be made by defendant – material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B).

FOURTH CAUSE OF ACTION

(False Claims Act: Making or Using False Record
Or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(7) and 31 U.S.C. § 3729(a)(1)(G))

177. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

178. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants knowingly made, used or caused to be made or used false records or false statements – *i.e.*, the false certifications made or caused to be made by defendant – material to an obligation to pay or transmit money to the Government or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

FIFTH CAUSE OF ACTION

(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(3) and 31 U.S.C. § 3729(a)(1)(C))

179. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if full set forth herein.

180. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants conspired to make or present false or fraudulent claims, with the specific intent of defrauding the Government, and performed one or more acts to effect payment of false or fraudulent claims.

SIXTH CAUSE OF ACTION

(California False Claims Act)
(Cal. Govt. Code §§ 12651, *et seq.*)

181. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

182. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

183. By virtue of the acts described above, Defendants knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

184. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continue to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

185. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

186. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTH CAUSE OF ACTION

(Florida False Claims Act)
(Fla. Stat. Ann. §§ 68.081, *et seq.*)

187. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

188. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

189. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

190. The Florida State Government, unaware of the falsity of the records, statements

and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

191. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

192. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTH CAUSE OF ACTION

(New Jersey False Claims Act)
(N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*)

193. Relator repeats and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

194. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

195. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted and/or falsified material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

196. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or

conduct of Defendants as alleged herein.

197. By reason of the Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

198. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty allowed under the federal False Claims Act, 31 U.S.C. § 3729, for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

VIII. DEMANDS FOR RELIEF

WHEREFORE, Relator, on behalf of the United States Government, demands judgment against the Defendants, ordering that:

As to the Federal Claims:

a. Pursuant to 31 U.S.C. § 3729(a), Defendants pays 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 not less than $5,000 and not more than $11,000 or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729, *et seq*, and $50,000 for each violation of 42 U.S.C. § 1320a-7a(a)(7) of the Medicare/Medicaid Anti-Kickback Statute;

b. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law; and

d. Relator be awarded such other and further relief as the Court may deem to be just and proper.

As to the State Claims:

e. Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendant within each State, all as provided by:

Cal. Govt. Code § 12651;
Fla. Stat. Ann. § 68.082; and
N.J. Stat. Ann. § 2A:32C-3;

f. Relator be awarded his relator's share of any judgment to the maximum amount provided pursuant to:

Cal. Govt. Code § 12652(g)(2);
Fla. Stat. Ann. § 68.085; and
N.J. Stat. Ann. § 2A:32C-7;

g. Relator be awarded all costs and expenses associated with each of the pendent State claims, plus attorney's fees as provided pursuant to:

Cal. Govt. Code § 12652(g)(8);
Fla. Stat. Ann. § 68.086; and
N.J. Stat. Ann. § 2A:32C-8;

h. Relator and the State Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

Dated: October 22, 2015

/s/ Jeffrey S. Goddess

Jeffrey S. Goddess (No. 630)
ROSENTHAL, MONHAIT & GODDESS, P.A.
919 N. Market Street, Suite 1401
P.O. Box 1070
Wilmington, DE 19899-1070
jgoddess@rmgglaw.com
(302) 656-4433

David S. Stone (admitted *pro hac vice*)
Robert A. Magnanini
Amy Walker Wagner
Carolyn B. Rendell
STONE & MAGNANINI LLP
150 John F. Kennedy Pkwy, 4th Floor
Short Hills, New Jersey 07078
973-218-1111

Attorneys for Relator