IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNDER SEAL, Plaintiffs, v. UNDER SEAL, Defendant.	NO. 18-cv-11931-PBS JURY TRIAL DEMANDED **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730**

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, the STATES of ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, WISCONSIN, the COMMONWEALTHS OF MASSACHUSETTS, PUERTO RICO, VIRGINIA, and the DISTRICT OF COLUMBIA, *ex rel.* JAMES LANDOLT, Plaintiffs, vs. MALLINCKRODT ARD LLC, f/k/a MALLINCKRODT ARD, INC., f/k/a QUESTCOR PHARMACEUTICALS, INC., Defendant.	Civil Action No. 18-cv-11931-PBS JURY TRIAL DEMANDED **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730**

FIRST AMENDED COMPLAINT FOR VIOLATIONS

OF THE FEDERAL AND STATE FALSE CLAIMS ACTS

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I. INTRODUCTION

1. This is an action brought by James Landolt ("Relator") as a *qui tam* relator on behalf of the United States of America and certain States (the "States" or "*Qui Tam* States") against Mallinckrodt ARD LLC, f/k/a Mallinckrodt ARD, Inc., f/k/a Questcor Pharmaceuticals, Inc. ("Mallinckrodt" or "Defendant"), pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq*. (the "FCA" or the "Federal FCA"), as amended by the Fraud Enforcement and Recovery Act of 2009 and the Patient Protection and Affordable Care Act of 2010, and the State False Claims Act statutes identified herein ("State *Qui Tam* statutes" or "State FCAs"), to recover damages, penalties, attorneys' fees and costs, and other relief.

2. Defendant manufactures and sells H.P. Acthar® Gel (repository corticotropin) Injection ("Acthar") and has done so at all relevant times for purposes of this action. Mallinckrodt plc, Defendant's parent company, acquired rights to the drug after purchasing Questcor Pharmaceuticals, Inc. ("Questcor") in August 2014. Both before and after Questcor's acquisition, Defendant has used and is continuing to use the *incorrect* base date Average Manufacturer Price ("base AMP") for Acthar in reporting and paying rebates to the Medicaid Drug Rebate ("MDR") Program. Mallinckrodt has knowingly done so in order to defraud the United States Government and the States and avoid payment of hundreds of millions of dollars in Medicaid rebate payments under the Medicaid Drug Rebate Program.

3. Defendant's conduct alleged herein violates the Federal and State False Claims Acts. The Federal False Claims Act ("FCA") was originally enacted during the Civil War to deal with unscrupulous military contractors. Congress substantially amended the FCA in 1986—and, again, in 2009 and 2010—to enhance the ability of the Government to recover losses sustained as a result of fraud against it. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without

fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

4. The FCA prohibits, *inter alia*: having possession, custody, or control of Government money or property and knowingly delivering or causing to be delivered less than all of that money or property; and knowingly making, using, or causing 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 concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government. 31 U.S.C. §§ 3729(a)(1)(D) and (G). Any person who violates the FCA is liable for a civil penalty for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1); Civil Monetary Penalties Inflation Adjustment for 2017, 82 Fed. Reg. 9131, 9133, *available at* https://www.federalregister.gov/documents/2017/02/03/2017-01306/civil-monetary-penalties-inflation-adjustment-for-2017. The State FCAs contain comparable or analogous provisions.

5. The Federal and State FCAs allow any person having information about an FCA violation to bring an action on behalf of the Government, and to share in any recovery. The FCA requires that the Complaint be filed under seal (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit. The person bringing the action is known under the FCA as the "Relator."

6. Based on the Federal FCA and comparable provisions of the State FCAs, *qui tam* Plaintiff-Relator seeks, through this action, to recover damages and civil penalties arising from Mallinckrodt's knowing fraud against the United States and the States including through the Medicaid Program.

7. The allegations in this action have not been publicly disclosed within the meaning of the Federal FCA, as amended, 31 U.S.C. § 3730(e)(4), or analogous provisions of the State FCAs. In the alternative, if the Court finds that there was a public disclosure of such allegations before the filing of this action, Relator is an "original source" as that term is used in the Federal and State FCAs. *Id.*

8. Prior to the filing of this action, Plaintiff-Relator made substantive disclosures to the Government of facts and evidence underlying the allegations in this action.

9. This action has been filed *in camera* and under seal pursuant to the requirements of the Federal and State FCAs.

II. Jurisdiction and Venue

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732, which confers jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court has original and supplemental jurisdiction over the State law claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367 because this action is brought under State laws for the recovery of funds paid by the *Qui Tam* States and arises from the same transaction or occurrence as the claims brought on behalf of the United States under 31 U.S.C. § 3730.

11. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant resides in, transacts business in and/or has committed acts related to the allegations in this action in the District of Massachusetts.

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1391, and 28 U.S.C. § 1395(a), because Defendant resides in and/or transacts business in this District by, among other things, selling pharmaceuticals, including Acthar directly or through

third parties, such as wholesalers, with the knowledge that those pharmaceuticals will be dispensed to persons covered by the Medicaid and other Government Health Care Programs.

III. Parties

13. Plaintiffs the United States of America and the *Qui Tam* States are the real parties in interest with respect to the Federal and State False Claims Act *qui tam* claims. Relator James Landolt is pursuing causes of action on behalf of the named Plaintiffs the United States and the States on the FCA *qui tam* claims set forth herein pursuant to the Federal FCA, 31 U.S.C. § 3730(b), and comparable provisions of the State FCAs.

14. Relator James Landolt is a natural person who is a citizen of the United States. He formerly worked in Hazelwood, Missouri, at Mallinckrodt plc's principal United States office. At the time he resigned from Mallinckrodt, Relator reported to Mallinckrodt plc's Senior Vice President, Finance, and Corporate Controller. His title was Director of Internal Controls, Gross to Net Accounting, and Government Reporting. The Government Reporting group's responsibilities included reporting of data to the MDR Program. Relator has personal knowledge of the drug at issue in this action and the allegations herein. Additional information regarding Relator's knowledge of the allegations herein has been provided to the Government pursuant to the Federal and State FCAs.

15. On August 14, 2014, Mallinckrodt plc acquired Questcor Pharmaceuticals, Inc., after which Questcor became a wholly-owned indirect subsidiary of Mallinckrodt plc. Questcor changed its name to Mallinckrodt ARD, Inc., on July 27, 2015. Thereafter, on January 26, 2019, Mallinckrodt ARD, Inc., converted to Mallinckrodt ARD LLC.

16. Defendant Mallinckrodt ARD LLC is a California limited liability company with its principal place of business at 1425 U.S. Route 206, Bedminster, NJ 07921. This is the headquarters location for Mallinckrodt's specialty brand business, which includes Acthar.

IV. Federal and State False Claims Acts

17. The Federal FCA creates liability for "any person who," among other things:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

c. "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C).

d. "has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property." 31 U.S.C. § 3729(a)(1)(D).

e. "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)(G).

18. The FCA further provides that any person who violates the FCA "is liable to the United States for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amounts range from a minimum of $5,500 to a maximum of $11,000. *See* 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, *47103 (1999). For violations occurring on or after November 2,

2015, the civil penalty amounts range from a minimum of $11,181 to a maximum of $22,363.28 C.F.R. § 85.5.

19. The FCA provides that "the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1). The FCA does not require proof that the defendant specifically intended to commit fraud. *Id.* Unless otherwise indicated, whenever the word "know" and similar words indicating knowledge are used in this Amended Complaint, they mean "knowing" or "knowingly" as defined in the FCA.

20. The FCA provides that "the term 'claim' – (A) means 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).

21. The FCA provides that "the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3) (emphasis added). Moreover, in the

health care context, such as Medicare and Medicaid, the term "obligation" is further defined as "Any overpayment retained by a person after the deadline for reporting and returning the overpayment...is an obligation (as defined [in the FCA])", and an overpayment must be reported "By the later of ...60 days after the date on which the overpayment was identified...or the date any corresponding cost report is due, if applicable." Patient Protection and Affordable Care Act, March 23, 2010 ("PPACA"), Pub. L. 111-148 (Mar. 23, 2010), Section 6404(a), codified at 42 U.S.C. § 1128J9(d). *See also* 42 U.S.C. § 1320a-7k(d).

22. The FCA provides that "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

23. Additionally, many States have passed False Claims Act laws, which in most instances closely track the Federal FCA. The State FCAs apply, *inter alia,* to the state portion of Medicaid losses caused by false or fraudulent Medicaid claims to the jointly federal-state funded Medicaid program and failure to report and return any overpayments therefrom. The Defendant's acts alleged herein also constitute violations of the Alaska Medical Assistance False Claims and Reporting Act, 2016 Alaska Sess. Laws Ch. 25 (S.B. 74) § 09.58.010, *et seq.* (repealed non-retroactively by sunset effective July 1, 2019); the California False Claims Act, Cal. Govt. Code §§ 12650, *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. 25.5-4-303.5, *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274, *et seq.*; the Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, §§ 1201, *et seq.*; the Florida False Claims Act, Fla. Stat. §§ 68.081, *et seq.*; the Georgia Medicaid False Claims Act, Ga. Code. Ann. §§ 49-4-168, *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21, *et seq.*; the Illinois False Claims Act, 740 Ill. Comp. Stat. §§ 175/1, *et seq.*; the Indiana Medicaid False Claims and

Whistleblower Protection Act, Ind. Code §§ 5-11-5.7, *et seq.*; the Iowa False Claims Act, Iowa Code §§ 685.1, *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:437.1, *et seq.*; the Maryland False Health Claims Act, Md. Code Ann. Health-Gen §§ 2-601, *et seq.*; the Massachusetts False Claims Act, Mass. Ann. Laws Ch. 12 §§ 5A, *et seq.*; the Michigan Medicaid False Claims Act, Stat. Mich. Comp. Laws Serv. §§ 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 Submission of False Claims to State and Local Government Act, Nev. Rev. Stat. §§ 357.010, *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1, *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § § 27-14-1, *et seq.*; the New York False Claims Act, N.Y Fin. Law §§ 187, *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605, *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. §§ 63-5053 (2007), *et seq.*; the Fraudulent Claims to Programs, Contracts, and Services of the Government of Puerto Rico Act, P.R. Laws Ann. tit. 32, § 2934, *et seq.* (2018); the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181, *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§ 36.001, *et seq.*; the State of Vermont False Claims Act, 32 V.S.A. Chapter 7, Subchapter 8, *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1, *et seq.*; the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005, *et seq.*; the Wisconsin False Claims For Medical Assistance Act, Wis. Stat. Ann. §§ 20.931, *et seq.* (repealed non-retroactively, effective July 14, 2015); and the District of Columbia False Claims Act, D.C. Code Ann. §§ 2-381.01, *et seq.* Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

V. Medicaid Drug Rebate Program

24. The Medicaid Program, Title XIX of the Social Security Act ("SSA"), 42 U.S.C. §§ 1396, *et seq.* (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services ("HHS") through its Centers for Medicare and Medicaid Services ("CMS"). Medicaid was designed to assist participating states in providing medical services, durable medical equipment, and prescription drugs to financially needy individuals that qualify for Medicaid. Medicaid may serve as the primary insurer, or in some instances as the secondary insurer (*e.g.*, with Medicare or private insurance providing primary coverage).

25. Each State has its own Medicaid program, which is partially funded by the United States Government. Medicaid sets forth minimum requirements for State Medicaid Programs to meet to qualify for federal funding and each participating State adopts its own plan and regulations governing the administration of the state's Medicaid program.

26. The States and the United States share reimbursement costs. The Federal Government's share is referred to as the Federal Medical Assistance Percentage ("FMAP") or Federal Financial Participation ("FFP") and varies depending upon the per capita income of each State. https://aspe.hhs.gov/federal-medical-assistance-percentages-or-federal-financial-participation-state-assistance-expenditures. The FMAP consists of a minimum of 50% up to a maximum of about 75%.

27. The majority of States award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the State Medicaid Programs. Before the beginning of each calendar quarter, each State submits to CMS an estimate of its

Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each State will be permitted to draw down as it incurs expenditures during the quarter. The State then draws down federal funding as actual provider claims are presented for payment. After the end of each quarter, the State then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). *See* 42 C.F.R. § 430.30.

28. In order to ensure that Medicaid does not pay more for prescription drugs than private payers, Congress enacted the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r–8, effective January 1, 1991. The stated purpose of the Program was to give the State Medicaid Programs the "benefit of the best price for which a manufacturer [sold] a prescription drug to … [a] private purchaser." H.R. Rep. No. 101-881 (1990). At all times relevant to this action, drug manufacturers have been required to participate in the Medicaid Drug Rebate Program in order for their drugs to be covered by Medicaid. 42 U.S.C. § 1396r–8(a)(1).

29. As part of their participation in the Medicaid Drug Rebate Program, drug manufacturers are obligated to execute a national rebate agreement with the Secretary of HHS. https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html. A sample national drug Rebate Agreement is at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/samplerebateagreement.pdf. *See generally* 42 U.S.C. §1396r-8(a)(1). The terms of the rebate agreement are set by the statute. 42 U.S.C. §1396r-8(b).

30. CMS and HHS oversee Medicaid jointly with agencies in each State. Each named Plaintiff State participates in Medicaid. All "manufacturers" of "covered outpatient drugs" are

required to enter into rebate agreements with each state Medicaid plan and provide information to CMS concerning their covered drugs. CMS administers the Medicaid Drug Rebate Program.

31. The statute defines the term "manufacturer" to mean "any entity engaged in—(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products." 42 U.S.C. § 1396r-8(k)(5).

32. A "covered outpatient drug" is defined as a drug approved under Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 ("FDCA"). 42 U.S.C. § 1396r-8(k)(2). Each covered outpatient drug is assigned a unique national drug code ("NDC") number. The NDC generally is an eleven-digit code consisting of the manufacturer's labeler code, the drug's product code, and the package code. *See* 42 C.F.R. § 447.502.

33. All participating manufacturers are obligated to pay specified rebates to the States, determined by a formula set forth in the MDR statute. 42 U.S.C. § 1396r-8(c). Manufacturers are responsible for submitting the correct product classification, along with accurate pricing data, to CMS on a quarterly basis for each dosage form and strength of the product so that CMS and the States can calculate the amount of rebates that are owed by the manufacturer; required data includes Average Manufacturer Price ("AMP") and Best Price. *See generally* 42 U.S.C. § 1396r-8(k)(1) and 41 C.F.R. § 447.504 (definition of AMP); 42 U.S.C. § 1396r-8(c)(1)(C) and 42 C.F.R. § 447.505(a) (definition of Best Price); 42 U.S.C. § 1396r-8(b)(3) (manufacturer price reporting); Medicaid Rebate Agreement §§ I(a),(d); II(e),(f), sample at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-

drugs/downloads/samplerebateagreement.pdf. AMP and Best Price are then used to calculate the rebate owed by a manufacturer to the States under the Medicaid Drug Rebate Program. This pricing data is generally submitted by the drug manufacturers through CMS's Drug Data Reporting ("DDR") for Medicaid System.

34. Manufacturers are obligated to pay rebates on a quarterly basis to States. The amount received by a State Medicaid Program in rebates is considered a reduction in the total amount expended under any given State's plan. Thus, the less a State receives in rebates, the more the Federal Government must pay to each State (because the Federal Government contributes a set percentage of the total amount each State expends on Medicaid). 42 USC § 1396b(a)(1); 42 USC § 1396r-8(b)(1)(B). *See generally* https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html. (these rebates "are shared between the states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program").

35. The rebate owed consists of two components: a basic rebate and an additional rebate, each of which is calculated based in part on the AMP of the drug. 42 U.S.C. § 1396r-8(c)(1)-(3). The amount of the rebates owed by a drug manufacturer is based on a statutory formula and varies depending on whether the drug is classified a "single source," an "innovator multiple source," or a "non-innovator" drug. *Id. See also* https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html; https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/index.html.

36. Acthar is a single source drug. For single source (and multiple source innovator drugs), the basic rebate is calculated using AMP and Best Price, and the additional rebate is

calculated by subtracting the base AMP from the current quarter AMP. The base AMP is the inflation-adjusted AMP for each dosage form and strength of the drug *when it was first sold* and it is intended to rebate the amount that a manufacturer has increased its drug prices beyond the amount necessary to account for inflation. *See* 42 U.S.C. § 1396r-8(c)(2)(A)-(B); 42 C.F.R. § 447.509(a)(2). Under the statute, there can only be one base AMP for each dosage form and strength of a covered outpatient drug. 42 U.S.C. § 1396r-8(c)(2)(A).

VI. Facts and Allegations

A. Introduction

37. Questcor acquired Acthar in 2001, when the price of the drug was reportedly around $40 per vial. In August 2007, Questcor dramatically raised Acthar's price from $1,650 to $23,269 per vial. The price increases continued. When Mallinckrodt acquired Questcor in 2014, Acthar reportedly was priced at about $32,000 per vial. Nevertheless, since the acquisition, Mallinckrodt has raised the price of Acthar even more, reportedly to over $40,000 per vial currently.

38. Because these large price increases far exceeded the rate of inflation, the additional rebate that Mallinckrodt owed to the MDR Program also increased significantly. *See* ¶ 36 above. Mallinckrodt, however, knowingly submitted false and fraudulent information to the MDR Program in order to avoid paying the proper rebate amount for Acthar and thereby increase Mallinckrodt's profits.

39. For each and every quarter from the beginning of 2013 through the present and continuing, Mallinckrodt has knowingly paid the MDR Program less than it owes in rebates for Acthar and instead retained and used for its benefit funds that belong to the Government.

40. For each and every quarter from the beginning of 2013 through the present and continuing, Mallinckrodt has knowingly concealed its obligation to pay the MDR Program what it owes in rebates for Acthar.

41. For each and every quarter from the beginning of 2013 through the present and continuing, Mallinckrodt has knowingly and improperly avoided and decreased its obligation to pay the MDR Program what it owes in rebates for Acthar.

42. It did so from 2013 to April 2016 after misleadingly telling CMS that a 2010 FDA approval for Acthar to treat infantile spasms had been under a new National Drug Application (NDA), without disclosing that the NDA number was a temporary one used solely for the FDA's administrative purposes and not approval of a new drug. After receiving this incomplete and misleading information, CMS allowed Mallinckrodt to reset Acthar's base date AMP. As a result, Mallinckrodt reported and paid dramatically-reduced rebates to the MDR Program, beginning in the first quarter of 2013.

43. Mallinckrodt knowingly and improperly retained hundreds of millions of additional dollars in unpaid rebates even after CMS directed Mallinckrodt in April 2016 to correct Acthar's product data in the DDR system to reflect that Acthar was marketed under its original NDA.

44. Mallinckrodt's deliberate refusal to correct its reporting for Acthar, its false quarterly statements and reports to the MDR Program, and its knowing retention of Government funds have continued despite multiple demands by CMS that it pay the MDR Program what it owes.

B. Acthar Background

45. Mallinckrodt manufactures and sells Acthar. The drug has been on the market since 1952 when it was approved for multiple indications by the United States Food and Drug Administration ("FDA") under the FDCA. This approval was under NDA 008372.

46. In 1977, the FDA approved additional indications for Acthar pursuant to a supplemental application, sNDA 08-372/S-016.

47. In or about 1979, the FDA approved Acthar for treatment of multiple sclerosis exacerbations pursuant to a supplemental application, sNDA 08-372/S-018.

48. In October 2010, the FDA approved the addition of infantile spasms to Acthar's approved indications. Mallinckrodt sought this approval pursuant to a supplemental application, sNDA 08-372/039.

49. Acthar now has 19 FDA-approved indications, including infantile spasms. The NDC currently assigned to Acthar is 63004-8710-01.

50. Since its approval in 1952, Acthar has been the same drug. Its chemical composition, dosage form, and strength have not changed.

51. Since its approval in 1952, Acthar has been marketed under NDA 008372.

52. At all times relevant to this action, Mallinckrodt (including Questcor, prior to its acquisition by Mallinckrodt) had entered into MDR rebate agreements and PPAs with the Secretary of HHS. Mallinckrodt is a "manufacturer" and Acthar is a single source "covered outpatient drug" within the meaning of the MDR Program. As such, Mallinckrodt is responsible for submitting accurate data concerning Acthar each quarter to CMS.

53. In particular, under the MDR, Mallinckrodt is required to use and submit to CMS baseline data for Acthar, including the base AMP, that matches the baseline information of the *NDC that was originally used for marketing Acthar under the original NDA*. *See* Medicaid Drug

Rebate Program Notice, Release Nos. 90, 48, 43, 38, and 26. These releases reflect CMS's longstanding interpretation of the MDR statute and repeatedly explain that the base AMP "MUST follow the NDA of the product." Release No. 26 (emphasis in original).

54. According to the FDA, that original NDA is 008372; the NDC associated with that NDA is 63004-7731-01. At all times relevant to this action, Mallinckrodt knew both of these facts.

C. Mallinckrodt Knew That The FDA's Use Of A Temporary Administrative NDA To Process A Supplement To Acthar's Original NDA Was Not Approval Of A New Drug.

55. In June 2006, Mallinckrodt submitted to the FDA a supplemental New Drug Application ("sNDA") seeking approval of Acthar for a new indication – infantile spasms. Mallinckrodt submitted this sNDA as an efficacy supplement under Acthar's *original* New Drug Application, NDA 008372, as "sNDA 08-372/S-039." (The "S-039" indicates that it was the 39th supplement under NDA 008372.) As noted above, ¶¶ 46-47, the FDA had previously approved other new indications for Acthar through supplemental NDAs.

56. When a manufacturer submits a new drug for FDA approval, the FDA assigns a unique six-digit NDA number. Acthar's is NDA 008372. Full NDAs require very detailed submissions for each of the drug's proposed indications. Applications to add a new indication to an already-approved drug (such as the one that Mallinckrodt submitted for Acthar in 2006) are much more limited in scope and are submitted as supplements to the drug's *already-existing* NDA. *See* 21 C.F.R. § 314.3(b) (defining "efficacy supplement" to include a supplement to an approved NDA proposing to add or modify an indication).

57. Mallinckrodt correctly submitted its 2006 application to add infantile spasms to Acthar's approved indications as a *supplemental* application to NDA 008372.

58. After Mallinckrodt submitted its supplement to NDA 008372, the FDA assigned a temporary new NDA number (known then as a "Type 6 NDA") but only for its own internal tracking purposes – NDA 022432. This was done because the indication for which Mallinckrodt sought approval – infantile spasms – was to be reviewed by a different division within FDA than the one responsible for the original NDA. The FDA's Division of Neurology Products assumed responsibility for review of Mallinckrodt's application from the Division of Metabolism and Endocrinology Products.

59. The FDA's administrative and correspondence file for Mallinckrodt's application states that the sNDA 008372 application was converted to a Type 6 NDA and assigned NDA 22-432 in 2008. NDA 22-432 FDA Administrative and Correspondence Documents ("FDA Admin. Docs."), Memorandum (August 8, 2008), "Creating Type 6 NDA." The administrative and correspondence file is available at:

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s000AdminCorres.pdf.

60. Another memorandum in the administrative file likewise notes that Mallinckrodt's efficacy supplement was submitted originally to NDA 008372 but later redesignated as a Type 6 NDA, explaining:

> A Type 6 NDA is an efficacy supplement that is designated in CDER's [Center for Drug Evaluation and Research's] database as a new NDA and assigned a new NDA number *for administrative purposes (e.g., to facilitate the review of a supplement for an indication for which the scientific expertise lies in a division different from the parent division for the original application*).

"FDA Admin. Docs.," Memorandum (August 31, 2010), "NDA 22-432 for H. P. Acthar Gel" (emphasis added). *See also* FDA Office of Pharmaceutical Quality, Manual of Policies and Procedures 8018.2, "NDA Classification Codes," p. 6 (Type 6 NDAs were assigned to applications received prior to July 27, 2009, "for a drug product that duplicates a drug product

already approved or marketed in the United States by the same applicant, except that it is intended for a new indication or claim").

61. The FDA informed Mallinckrodt in 2008 that this NDA had been created for administrative purposes.

62. After the FDA assigned Mallinckrodt's supplemental application NDA 022432 as an administrative tracking number, both the FDA and Mallinckrodt continued to treat it as a supplement to NDA 008372.

63. On December 23, 2009, the FDA's Division of Neurology Products acknowledged receipt of Mallinckrodt's "resubmission to [its] *supplemental* new drug application for [Acthar]." FDA Admin. Docs., Letter from Susan Daugherty to Questcor (December 23, 2009), "Acknowledgement Class 2 Response" (emphasis added). Because review of the supplemental NDA had been transferred to the Division of Neurology Products, this and other FDA correspondence relating to Mallinckrodt's supplemental application referred to tracking number NDA 22-432.

64. The FDA approved Acthar for infantile spasms on October 15, 2010. In its approval letter, the FDA referred Mallinckrodt back to its supplemental application dated June 16, 2006, which was submitted under Acthar's *original* NDA 008372. The FDA approved that original application, as amended; it did not approve Acthar as a new drug with a new NDA.

65. The FDA's letter emphasized that the approval was as a *supplement* to the original NDA 008372. Under "REPORTING REQUIREMENTS," the FDA's approval specifically stated: "All ... submissions relating to the product should be addressed to the original **NDA 008372** for this drug product, not to this NDA [022432]. In the future, do not make submissions to this NDA except for the final printed labeling requested above." NDA 022432

(October 15, 2010), p. 5 (emphasis in original). Furthermore, the FDA required that any submission relating to Risk Evaluation and Mitigation Strategy assessments or proposed modifications for the drug should reference **NDA 008372/NEW SUPPLEMENT FOR NDA 008372/ NEW SUPPLEMENT (NEW INDICATION FOR USE) FOR NDA 008372**. *Id.* at p. 4 (emphasis in original).

66. In its press release announcing the FDA's decision, Mallinckrodt itself acknowledged that the FDA had approved its "*supplemental* new drug application (sNDA) for [Acthar] in the treatment of infantile spasms." Questcor Pharmaceuticals, Inc. Press Release, October 15, 2010 (emphasis added), available at: https://www.prnewswire.com/news-releases/fda-approves-hp-acthar-gel-for-the-treatment-of-infantile-spasms-105024204.html.

67. Mallinckrodt correctly continued to list the applicable NDA for Acthar as 008372 (the original NDA) in the FDA Online Label Repository after Acthar was approved for the infantile spasms indication.

68. In addition, the label that the FDA required after approving the infantile spasms indication states that Acthar was approved *in 1952*. Acthar product label dated October 2010, available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s000LBL.pdf. In other words, the FDA did not approve a new drug in 2010 for treatment of infantile spasms; it was the same Acthar as had been approved for previous indications under NDA 008372.

69. All supplemental NDAs that Mallinckrodt has submitted for Acthar – before and after October 2010 – have been under its original NDA 008372, never 022432. For example:

a. In May 2011, Mallinckrodt submitted a supplemental application (NDA 008372/S-044) to associate Achar's infantile spasms indication with its original

NDA number 008372 "*since the tracking NDA number will no longer be used.*" (Emphasis added.)

b. In April 2012, Mallinckrodt submitted a supplemental application (NDA 008372/S-045) seeking to eliminate the FDA's requirement for an approved Risk Evaluation and Mitigation Strategy (REMS), which the FDA imposed when approving Acthar for infantile spasms in October 2010. The REMS applied only to Acthar's infantile spasms indication and was required due to a concern that infants were particularly at risk for serious adverse events.

c. Since acquiring Questcor in 2014, Mallinckrodt has submitted supplements to the FDA, all using Acthar's original NDA 008372.

70. In sum, Mallinckrodt at all times understood that NDA 022432 was a temporary tracking number used to approve its supplement to Acthar's original NDA, not approval of a new drug.

71. Mallinckrodt's knowledge of this is evident from:

- FDA's regulations, which make clear that an application to add an indication without modifying the drug itself is to be submitted as an sNDA and does not result in a new drug with a new NDA;
- Mallinckrodt's own conduct in submitting the application as NDA 008372/S-039 – a supplement – rather than a new NDA;
- The Type 6 designation for NDA 022432, indicating that it was assigned for the FDA's internal administrative purposes as a temporary tracking number;
- FDA instructions to Mallinckrodt that all submissions relating to Acthar were to be addressed to the original NDA 008372 as supplements, *not* to NDA 022432;
- Mallinckrodt's press release announcing the FDA's approval of its "*supplemental* new drug application (sNDA)" for Acthar in treatment of infantile spasms (emphasis added);
- Mallinckrodt's continued listing of 008372 as the applicable NDA for Acthar in the FDA Online Label Repository after October 2010;
- Mallinckrodt's practice of submitting all supplements relating to Acthar to the FDA under its original NDA 008372, including those relating to the infantile spasms indication approved in October 2010; and,

- Mallinckrodt's express acknowledgement in its May 2011 supplemental application (NDA 008372/S-044) that "the tracking NDA number [022432] will no longer be used."

D. Mallinckrodt Misleadingly Presented The FDA's 2010 Approval To CMS As A New NDA For A New Drug

72. As described above, Mallinckrodt fully recognized that Acthar had been approved under NDA 008372. Consistent with that view, following the FDA's October 2010 approval for the infantile spasms indication, it continued submitting quarterly data to the MDR Program under NDC 63004-7731-01, the NDC number associated with Acthar's *original* NDA, 008372. Thus, Mallinckrodt knew that the correct base AMP for Acthar was linked to its original NDA.

73. In May 2012, however, Mallinckrodt adopted a strategy designed to dramatically reduce its rebate obligations and make Acthar significantly more lucrative. It wrote to CMS asserting that the FDA's 2010 approval of Acthar for treating infantile spasms justified establishing a new base AMP for Acthar.

74. This was wrong because, as previously noted (¶ 36 above), the MDR Program requires that drug manufacturers submit base AMP data based on a drug's original NDA.

75. This was wrong because Acthar was the same drug that it had been prior to the 2010 approval. Its composition, dosage form, and strength had not changed. All the October 2010 approval did was authorize a new indication for Acthar (in addition to 18 others for which it already was approved), update its label, and require a REMS for the new infantile spasms indication (a requirement that Mallinckrodt had petitioned the FDA the previous month to remove, which the FDA agreed to do in July 2012 – *see* ¶ 81 below).

76. This was wrong because the FDA had made clear in its approval that NDA 022432 was not an ongoing new NDA for Acthar. To the contrary, the FDA stated expressly that it was not to be used thereafter.

77. This was wrong because Acthar – both before and after the 2010 approval – was marketed under NDA 008372. The FDA's Orange Book, the authoritative reference guide to drug products approved by the FDA, listed Acthar as associated with NDA 008372 at the time of the 2012 letter and does so to this day. Moreover, Mallinckrodt itself continued to list Acthar under NDA 008372 in the FDA Online Label Repository after October 2010 (until self-servingly changing the listing to NDA 022432 in July 2016 after CMS had notified Mallinckrodt that it was incorrectly reporting Acthar's product data to Medicaid's DDR system – *see* ¶¶ 85, 91 below).

78. Mallinckrodt failed to inform CMS that NDA 022432 was for administrative purposes only and that the FDA had directed that it no longer be used. Mallinckrodt failed to disclose to CMS that it had submitted its application for the infantile spasms indication to the FDA as a *supplement* to NDA 008372 and had acknowledged it as such when announcing the approval. Mallinckrodt also failed to disclose to CMS that – following the 2010 approval – it had itself been submitting supplemental NDAs for Acthar to the FDA under its *original* NDA 008372.

79. Rather than disclosing the accurate FDA history to CMS, Mallinckrodt asserted that the FDA's approval had significantly changed the conditions under which Acthar would be marketed and distributed and that the FDA had approved Acthar under a new NDA 022432.

80. Mallinckrodt's letter is misleading because it omits all relevant context about how NDA 022432 came to be assigned to Mallinckrodt's supplemental application. It also is misleading because it suggests that NDA 022432 was the operative NDA for Acthar's marketing in 2012, when in fact the FDA had instructed Mallinckrodt back in 2010 that it was not to be

used thereafter. Moreover, as noted (¶ 69.a above), Mallinckrodt itself had acknowledged in 2011 that 022432 ("the tracking NDA number") would no longer be used.

81. Mallinckrodt also misleadingly cited the REMS requirement as a change representing a "significant revision ... in the conditions under which [Acthar] *will* be marketed and distributed" (emphasis added) without disclosing that it had submitted an application (NDA 008372/S-045) the previous month under Acthar's original NDA for the elimination of that requirement. While Mallinckrodt's letter was pending at CMS, the FDA eliminated the REMS requirement on July 6, 2012; however, Mallinckrodt failed to inform CMS of this development.

82. By letter dated August 6, 2012, CMS agreed to allow Mallinckrodt to report a new base AMP for Acthar. According to its letter and subsequent correspondence, CMS based its decision on Mallinckrodt's representation that the FDA had approved Acthar under a new NDA. CMS made clear that its decision was "limited to and based on the facts and information presented to [it]." As a result, Acthar was assigned a new NDC – 63004-8710-01.

83. Beginning with the first quarter of 2013, Mallinckrodt began submitting Acthar data to the MDR Program under NDC 63004-8710-01 and falsely and fraudulently reporting NDA 022432 as its FDA application number. In doing so, it improperly used a base AMP from approximately 2010 or later (which reflects Acthar's dramatic price increases) instead of a base AMP from many years earlier when the drug was more reasonably priced. By using the incorrect base AMP, Mallinckrodt thwarted the purpose of the additional rebate for single source and multiple source innovator drugs and paid hundreds of millions of dollars less than it owed in rebates to the MDR Program.

E. Mallinckrodt Has Deliberately Avoided Its Rebate Obligations Despite Repeated Directions By CMS To Correct Acthar's Base AMP Data

84. In late 2015, CMS learned the truth: that the only active NDA number for Acthar was 008372 (the original NDA) and that the administrative number temporarily assigned when it was approved for infantile spasms (022432) had been closed.

85. By written correspondence dated April 13, 2016, CMS notified Mallinckrodt that it was required to correct Acthar's NDA number in the DDR system to reflect that it was marketed under NDA 008372, not 022432. CMS told Mallinckrodt "to review and correct the reporting of its product data in DDR to ensure that accurate information is reported to the MDR program."

86. After Mallinckrodt received CMS's letter, Relator's supervisor, Mallinckrodt's Senior Vice President, Finance, and Corporate Controller, directed that the scope of Mallinckrodt's rebate liability be calculated. Upon learning that it was, at that time, over $200 million, his supervisor indicated that Mallinckrodt would never pay that much and instructed Relator and another individual to limit distribution and discussion of the liability calculation.

87. Mallinckrodt responded to CMS via email on May 10, 2016, and referred CMS to the correspondence between Questcor and CMS in 2012, which had resulted in Acthar getting a new NDC (63004-8710-01) and new base AMP. *See* ¶¶ 73-82 above.

88. CMS replied via email on June 2, 2016, rejecting Mallinckrodt's position and directing it again to correct Acthar's baseline data "so that the baseline information for the NDC matches the baseline information of the NDC that was originally used for marketing the product under the same NDA."

89. Prior to responding to CMS's email, Mallinckrodt updated the calculation of its rebate liability to include the period through the end of the first quarter of 2016. Mallinckrodt's updated rebate liability was estimated to be $265 million.

90. On July 6, 2016, Mallinckrodt responded to CMS's email, insisting that NDA 022432 "was, in fact, the correct FDA assigned application number for the approval of the product," without acknowledging that it was a temporary administrative number assigned to a supplemental NDA (which the FDA directed should not be used thereafter) or any of the other relevant FDA history cited above. Mallinckrodt also represented that it would "continue to research the points CMS has raised" and that it would "continue to look further into your correspondence, and [would] offer additional thoughts, as they may be helpful to you, at a later date when we have completed our work."

91. Mallinckrodt's only communication with CMS after its July 6, 2016 promise to "look into" the rebate issue and respond when it had "completed [its] work" was a July 29, 2016 email notifying CMS that it had changed Acthar's FDA Online Label Repository listing to NDA 022432. Prior to that (consistent with the FDA's direction and Acthar's history), Mallinckrodt had listed Acthar correctly under NDA 008372, the *original* NDA.

92. After hearing nothing further from Mallinckrodt, CMS contacted it again on March 20, 2017. CMS informed Mallinckrodt that it had confirmed with the FDA that NDA 022432 was a Type 6 NDA created for administrative purposes, which had been closed upon approval, and that Acthar was and always had been marketed under NDA 008372. CMS concluded by stating: "NDA 008372 for Acthar was approved on April 29, 1952, therefore, the baseline data for the drug that is marketed under that NDA would be based on data from

9/30/1990 *as the approval of NDA 022432 in 2010 was not for approval of a new drug.*" (Emphasis added.)

93. In an April 14, 2017 letter, Mallinckrodt again refused to accept CMS's position, insisting that the agency's conclusion in 2012 (based on Mallinckrodt's misleading letter) had been correct. It also promised to have ongoing dialogue and engagement with CMS on the rebate issue.

94. In spring 2017, Relator spoke with his supervisor to express concerns that Mallinckrodt was not responding appropriately to CMS. His supervisor analogized the rebate issue to a taxpayer who realizes he has filed an incorrect tax return and owes back taxes, saying in essence that a taxpayer in that situation would not voluntarily repay the money but instead wait until the Internal Revenue Service demanded it.

95. Relator resigned and left Mallinckrodt in early July 2017.

96. In the time Relator worked at Mallinckrodt, he was not aware of any ongoing engagement between the company and CMS on the rebate issue other than the communications cited above. To the limited extent that the Government Reporting group responded to CMS on this issue, the substance of those communications was directed by Mallinckrodt's senior management.

97. Finally, on November 6, 2018, CMS notified Mallinckrodt that the company had failed to take any action to correct its reporting of incorrect base AMP data and directed it to do so within 30 days. CMS informed Mallinckrodt that, if it did not do so, it would consider Acthar to be out of compliance in the Medicaid Drug Data Reporting system as of December 17, 2018. CMS also stated that it might consider referring Mallinckrodt to the Department of Justice and/or the Office of the Inspector General of the Department of Health and Human Services.

98. Upon receipt of this notice, Mallinckrodt finally began engaging with CMS on the rebate issue. Over the next six months, Mallinckrodt continued to argue – contrary to the facts alleged above – that the FDA's 2010 approval of Mallinckrodt's supplemental application for Acthar justified a new base AMP for purposes of the MDR Program.

99. CMS rejected Mallinckrodt's arguments. On March 12, 2019, CMS wrote to Mallinckrodt and reiterated that the data reported to the DDR system for Acthar "should reflect the base date AMP for the drug that was first produced or distributed under new drug application (NDA) 008372." CMS stated that Mallinckrodt was underpaying Medicaid rebates for Acthar and directed it to complete and return a template to report the correct baseline information to the MDR Program.

100. Mallinckrodt once again failed to correct its reporting of Acthar's base AMP data to the DDR.

101. On May 10, 2019, CMS directed Mallinckrodt again to correct Acthar's base AMP data, adding that "further discussion regarding this issue would not be productive." CMS told Mallinckrodt to submit corrected information to CMS within 14 days or be deemed out of compliance in the DDR system. CMS again warned that it may refer the matter to the Department of Justice and/or the Office of the Inspector General of the Department of Health and Human Services.

102. Rather than comply, Mallinckrodt sued CMS on May 20, 2019, in the United States District Court for the District of Columbia, 19-cv-01471-TFH. In that case, Mallinckrodt continues to insist that the temporary administrative tracking number used to approve Mallinckrodt's *supplemental* NDA for infantile spasms entitles it to establish a new base AMP for Acthar (and *all* of its approved indications).

103. The following day, Mallinckrodt publicly disclosed what its executives had known, and concealed, since 2016 – that CMS had notified Mallinckrodt years before that it was improperly reporting Acthar's base AMP to the MDR Program and had directed Mallinckrodt to correct its data in the DDR system going back to the beginning of 2013. Mallinckrodt estimated that the retroactive impact of changing Acthar's base AMP reporting would be up to $600 million. http://mallinckrodt.com/about/news-and-media/news-detail/?id=25776.

F. Mallinckrodt's Fraudulent Scheme Harms The Federal And State Governments

104. Despite the fact that the applicable NDA for Acthar is 008372 (the original NDA), Mallinckrodt knowingly has been and continues to submit to CMS baseline data (including base AMP) based upon the Type 6 NDA that the FDA used when approving its supplemental NDA for infantile spasms. As a result, Mallinckrodt is falsely and fraudulently reporting to the MDR Program that Acthar was approved in 2010 and first marketed in 2013.

105. By failing properly to report baseline data for Acthar, including the correct base AMP, Mallinckrodt has knowingly, in each and every quarter for Acthar beginning in 2013:
(1) submitted false, fraudulent, inaccurate and misleading information regarding Acthar;
(2) submitted incorrect and insufficient data for CMS properly to calculate Acthar rebates; and
(3) substantially underpaid rebates owed under the MDR Program.

106. Mallinckrodt's fraudulent scheme to retain Government funds and avoid meeting its obligations under the MDR Program has caused several hundred millions of dollars in damages to the United States and the States in the form of unpaid rebates. Its misconduct, and the resulting harm, are continuing.

107. Mallinckrodt's fraudulent scheme to retain Government funds and avoid meeting its obligations under the MDR Program also has caused State Medicaid Programs to submit false

information to CMS each quarter. Because Mallinckrodt's scheme caused the States to receive less in rebates than they are owed, the United States has paid more to State Medicaid Programs. *See* ¶¶ 26-27, 33-34 above. This harm is also continuing.

VII. CLAIMS FOR RELIEF

Count I

Federal False Claims Act – Conversion of Government Property or Money 31 U.S.C. § 3729(a)(1)(D)

108. Relator repeats and realleges and incorporates herein by reference the allegations set forth in the preceding paragraphs as though fully set forth herein.

109. This is a civil action brought by Relator, on behalf of the United States of America, against Defendant under the False Claims Act, 31 U.S.C. § 3730(b)(1), for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

110. The FCA, 31 U.S.C. § 3729(a)(1)(D), creates liability for a person who "has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property." Defendant has violated this provision of the FCA.

111. Pursuant to the FCA, Defendant is thus "liable to the United States Government for a civil penalty . . . , plus 3 times the amount of damages which the Government sustains because of the act of [Defendant]." 31 U.S.C. § 3729(a).

112. Defendant's misconduct has harmed the United States, including through underpaying rebates by hundreds of millions of dollars.

COUNT II

Federal False Claims Act – Reverse False Claims
31 U.S.C. § 3729(a)(1)(G)

113. Relator repeats and realleges and incorporates herein by reference the allegations set forth in the preceding paragraphs as though fully set forth herein.

114. This is a civil action brought by Relator, on behalf of the United States of America, against Defendant under the False Claims Act, 31 U.S.C. § 3730(b)(1), for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

115. The FCA, 31 U.S.C. § 3729(a)(1)(G), creates liability for any person who "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." Defendant has violated this provision of the FCA.

116. Pursuant to the FCA, Defendant is thus "liable to the United States Government for a civil penalty . . . , plus 3 times the amount of damages which the Government sustains because of the act of [Defendant]." 31 U.S.C. § 3729(a).

117. Defendant's misconduct has harmed the United States, including through underpaying rebates by hundreds of millions of dollars.

Count III

Alaska False Claims and Reporting Act
2016 Alaska Sess. Laws Ch. 25 § 09.58.010, *et. seq.*
(repealed but count applies to conduct occurring during the effective period of the statute)

118. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

119. This is a civil action brought by Relator, on behalf of the State of Alaska, against Defendant under the Alaska Medical Assistance False Claims and Reporting Act, 2016 Alaska Sess. Laws Ch. 25 § 09.58.010, *et. seq.* (Alaska FCA), for acts occurring prior to the non-retroactive repeal of that law.

120. The Alaska FCA, Ak St § 09.58.010(a)(4), creates liability for any medical assistance provider or recipient who "knowingly make[s], use[s], or cause[s] to be made or used, a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money or property to the medical assistance program." Defendant has violated this provision of the Alaska FCA.

121. Pursuant to the Alaska FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Ak St § 09.58.010(c).

Count IV

California False Claims Act
Cal. Gov't Code §§ 12650, *et seq.*

122. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

123. This is a civil action brought by Relator, on behalf of the State of California, against Defendant under the California False Claims Act, Cal. Gov. Code § 12652(c).

124. The California FCA, Cal. Gov. Code § 12651(a)(4), creates liability for any person who "[h]as possession, custody, or control of public property or money used or to be used by the state or by any political subdivision and knowingly delivers or causes to be delivered less than all of that property." Defendant has violated this provision of the California FCA.

125. The California FCA, Cal. Gov. Code § 12651(a)(7), creates liability for any person who "[k]nowingly 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 state or to any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision." Defendant has violated this provision of the California FCA.

126. Pursuant to the California FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Cal. Gov. Code § 12651(a)(1).

Count V

Colorado Medicaid False Claims Act
Colo. Rev. Stat. §§ 25.5-4-303.5, et seq.

127. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

128. This is a civil action brought by Relator, in the name of the State of Colorado, against Defendant pursuant to the State of Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306.

129. The Colorado FCA, Colo. Rev. Stat. § 25.5-4- 305(1)(c), creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the state in connection with the 'Colorado Medical Assistance Act' and knowingly delivers, or causes to be delivered, less than all of that property." Defendant has violated this provision of the Colorado FCA.

130. The Colorado FCA, Colo. Rev. Stat. § 25.5-4- 305(1)(f), creates liability for any person who "[k]nowingly 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 state in connection with the 'Colorado Medical Assistance Act', or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the 'Colorado Medical Assistance Act'." Defendant has violated this provision of the Colorado FCA.

131. Pursuant to the Colorado FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Colo. Rev. Stat. § 25.5-4- 305(1).

Count VI

Connecticut False Claims Act
Conn. Gen. Stat. §§ 4-274, *et seq.*

132. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

133. This is a civil action brought by Relator, in the name of the State of Connecticut, against Defendant pursuant to the State of Connecticut False Claims Act, Conn. Gen. Stat. § 4-277.

134. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(4), provides that no person shall "[h]aving possession, custody or control of property or money used, or to be used, by the state relative to a state-administered health or human services program, knowingly deliver, or cause to be delivered, less property than the amount for which the person receives a certificate or receipt." Defendant has violated this provision of the Connecticut FCA.

135. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(7), provides that no person shall "[k]nowingly make, use or cause to be made or used, a false record or statement material to

an obligation to pay or transmit money or property to the state under a state-administered health or human services program." Defendant has violated this provision of the Connecticut FCA.

136. The Connecticut FCA, Conn. Gen. Stat. § 4-275(a)(8), provides that no person shall "[k]nowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the state under a state-administered health or human services program." Defendant has violated this provision of the Connecticut FCA.

137. Pursuant to the Connecticut FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Conn. Gen. Stat. § 4-275(b).

Count VII

Delaware False Claims and Reporting Act
Del. Code Ann. Tit. 6 §§ 1201, *et seq.*

138. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

139. This is a civil action brought by Relator, on behalf of the Government of the State of Delaware, against Defendant under the State of Delaware's False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1203(b)(1).

140. The Delaware FCA, Del. Code Ann. Tit. 6, §1201(a)(4), creates liability for any person who "[h]as possession, custody or control of property or money used or to be used by the Government and knowingly delivers or causes to be delivered, less than all of that money or property." Defendant has violated this provision of the Delaware FCA.

141. The Delaware FCA, Del. Code Ann. Tit. 6, §1201(a)(7), creates liability for any person who "[k]nowingly 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." Defendant has violated this provision of the Delaware FCA.

142. Pursuant to the Delaware FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Del. Code Ann. tit. 6, §1201(a).

Count VIII

District of Columbia False Claims Act
D.C. Code Ann. §§ 2.381.01, *et seq.*

143. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

144. This is a civil action brought by Relator, in the name of the District of Columbia, against Defendant under the District of Columbia False Claims Act, D.C. Code Ann. § 2-381.03(b)(1).

145. The D.C. FCA, D.C. Code Ann. § 2-381.02(a)(3), creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the District and knowingly delivers, or causes to be delivered, less than all of that money or property." Defendant has violated this provision of the D.C. FCA.

146. The D.C. FCA, D.C. Code Ann. § 2-381.02(a)(6), creates liability for any person who "[k]nowingly 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 District, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the District." Defendant has violated this provision of the D.C. FCA.

147. Pursuant to the D.C. FCA, Defendant is thus liable to the District for statutorily defined damages sustained because of the acts of Defendant and civil penalties. D.C. Code Ann. § 2-381.02(a).

Count IX

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

148. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

149. This is a civil action brought by Relator, on behalf of the State of Florida, against Defendant under the State of Florida's False Claims Act, Fla. Stat. § 68.083(2).

150. The Florida FCA, Fla. Stat. § 68.082(2)(d), creates liability for any person who "[h]as possession, custody, or control of property or money used or to be used by the state and knowingly delivers or causes to be delivered less than all of that money or property." Defendant has violated this provision of the Florida FCA.

151. The Florida FCA, Fla. Stat. § 68.082(2)(g), creates liability for any person who "[k]nowingly 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 state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendant has violated this provision of the Florida FCA.

152. Pursuant to the Florida FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Fla. Stat. § 68.082(2).

Count X

Georgia False Medicaid Claims Act
GA. Code Ann. §§ 49-4-168, *et seq.*

153. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

154. This is a civil action brought by Relator, in the name of the State of Georgia, against Defendant pursuant to the State of Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.2(b).

155. The Georgia FCA, Ga. Code Ann. § 49-4-168.1(a)(4), creates liability for any person who "[h]as possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and knowingly delivers, or causes to be delivered, less than all of such property or money." Defendant has violated this provision of the Georgia FCA.

156. The Georgia FCA, Ga. Code Ann. § 49-4-168.1(a)(7), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program." Defendant has violated this provision of the Georgia FCA.

157. Pursuant to the Georgia FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Ga. Code Ann. § 49-4-168.1(a).

Count XI

Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21, *et seq.*

158. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

159. This is a civil action brought by Relator, on behalf of the State of Hawaii and its political subdivisions, against Defendant under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-25(a).

160. The Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(3), creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the State and, intending to defraud the State or to willfully conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt." Defendant has violated this provision of the Hawaii FCA.

161. The Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(6), creates liability for any person who "[k]nowingly 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 State, or knowingly conceals, or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State." Defendant has violated this provision of the Hawaii FCA.

162. Pursuant to the Hawaii FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Haw. Rev. Stat. § 661-21(a).

Count XII

Illinois False Claims Act
740 Ill. Comp. Stat. §§ 175/1, *et seq.*

163. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

164. This is a civil action brought by Relator, on behalf of the State of Illinois, against Defendant under the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/4(b).

165. The Illinois FCA, 740 Ill. Comp. Stat. § 175/3(a)(1)(D), creates liability for any person who "has possession, custody, or control of property or money used, or to be used, by the State and knowingly delivers, or causes to be delivered, less than all the money or property." Defendant has violated this provision of the Illinois FCA.

166. The Illinois FCA, 740 Ill. Comp. Stat. § 175/3(a)(1)(G), creates liability for any person who "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 State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State." Defendant has violated this provision of the Illinois FCA.

167. Pursuant to the Illinois FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. 740 Ill. Comp. Stat. § 175/3(a).

Count XIII

Indiana False Claims Act
Ind. Code §§ 5-11-5.7, *et seq.*

168. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

169. This is a civil action brought by Relator, on behalf of the State of Indiana, against Defendant under the State of Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.7-4(a).

170. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(3), creates liability for any person who "has possession, custody, or control of property or money used, or to be used, by the state, and knowingly delivers, or causes to be delivered, less than all of the money or property." Defendant has violated this provision of the Indiana FCA.

171. The Indiana FCA, Ind. Code § 5-11-5.7-2(a)(6)(A)-(B), creates liability for any person who knowingly "(A) makes, uses, or causes to be made or used, a false record or statement concerning an obligation to pay or transmit money or property to the state; or (B) conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendant has violated this provision of the Indiana FCA.

172. Pursuant to the Indiana FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Ind. Code § 5-11-5.5-2(b).

Count XIV

Iowa False Claims Act
Iowa Code §§ 685.1, *et seq.*

173. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

174. This is a civil action brought by Relator, on behalf of the State of Iowa, against Defendant under the State of Iowa False Claims Act, Iowa Code § 685.3(2).a.

175. The Iowa FCA, Iowa Code § 685.2(1).d., creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the state and

knowingly delivers, or causes to be delivered, less than all of that money or property." Defendant has violated this provision of the Iowa FCA.

176. The Iowa FCA, Iowa Code § 685.2(1).g., creates liability for any person who "[k]nowingly 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 state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendant has violated this provision of the Iowa FCA.

177. Pursuant to the Iowa FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Iowa Code § 685.2(1).

Count XV

Louisiana Medical Assistance Programs Integrity Law
LA. Rev. Stat. Ann. §§ 46:437.1, *et seq.*

178. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

179. This is a civil action brought by Relator, on behalf of the State of Louisiana's medical assistance programs, against Defendant under the State of Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1.A.

180. The Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.C, provides that "[n]o person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs." Defendant has violated this provision of the Louisiana FCA.

181. Pursuant to the Louisiana FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. La. Rev. Stat. Ann. § 46:438.6.

Count XVI

Maryland False Health Claims Act
MD. Code Ann. Health-Gen. §§ 2-601, *et seq.*

182. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

183. This is a civil action brought by Relator, on behalf of the State of Maryland, against Defendant under the State of Maryland False Health Claims Act, Md. Code Ann. Health-Gen. § 2-604(a)(1).

184. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(4), provides that a person may not "[h]ave possession, custody, or control of money or other property used by or on behalf of the State under a State health plan or a State health program and knowingly deliver or cause to be delivered to the State less than all of that money or other property." Defendant has violated this provision of the Maryland FCA.

185. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(7), provides that a person may not "[k]nowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State." Defendant has violated this provision of the Maryland FCA.

186. The Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(8), provides that a person may not "[k]nowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State." Defendant has violated this provision of the Maryland FCA.

187. Pursuant to the Maryland FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Md. Code Ann. Health-Gen. § 2-602(b).

Count XVII

Massachusetts False Claims Act
Mass. Ann Laws Ch. 12, §§ 5a, *et seq.*

188. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

189. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendant under the Massachusetts False Claims Act, Mass. Ann. Laws, ch. 12, § 5C(2).

190. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(5), creates liability for any person who "has possession, custody or control of property or money used, or to be used, by the commonwealth or a political subdivision thereof and knowingly delivers, or causes to be delivered, to the commonwealth or a political subdivision thereof less than all of that property or money." Defendant has violated this provision of the Massachusetts FCA.

191. The Massachusetts FCA, Mass. Ann. Laws, ch. 12, § 5B(9), creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or to transmit money or property to the commonwealth or a political subdivision thereof, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the commonwealth or a political subdivision thereof." Defendant has violated this provision of the Massachusetts FCA.

192. Pursuant to the Massachusetts FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Mass. Ann. Laws, ch. 12, § 5B(a).

Count XVIII

Michigan Medicaid False Claims Act
Mich. Comp. Laws Serv. §§ 400.601, *et seq.*

193. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

194. This is a civil action brought by Relator, in the name of the State of Michigan, against Defendant under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(l).

195. The Michigan FCA, Mich. Comp. Laws. Serv. § 400.607(3), provides that "[a] person shall not knowingly make, use, or cause 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 state pertaining to a claim presented under the social welfare act." Defendant has violated this provision of the Michigan FCA.

196. Pursuant to the Michigan FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Mich. Comp. Laws. Serv. § 400.612.

Count XIX

Minnesota False Claims Act
Minn. Stat. §§ 15C.01, *et seq.*

197. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

198. This is a civil action brought by Relator, on behalf of the State of Minnesota and its political subdivisions, against Defendant under the State of Minnesota False Claims Act, Minn. Stat. § 15C.05(a).

199. The Minnesota FCA, Minn. Stat. § 15C.02(a)(4), creates liability for any person who "has possession, custody, or control of property or money used, or to be used, by the state or a political subdivision and knowingly delivers or causes to be delivered less than all of that money or property." Defendant has violated this provision of the Minnesota FCA.

200. The Minnesota FCA, Minn. Stat. § 15C.02(a)(7), creates liability for any person who "knowingly makes or 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 state or a political subdivision, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a political subdivision." Defendant has violated this provision of the Minnesota FCA.

201. Pursuant to the Minnesota FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Minn. Stat. § 15C.02(a).

Count XX

Montana False Claims Act
Mont. Code Ann. §§ 17-8-401, *et seq.*

202. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

203. This is a civil action brought by Relator, on behalf of the State of Montana, against Defendant under the State of Montana False Claims Act, Mont. Code Ann. § 17- 8-406(1).

204. The Montana FCA, Mont. Code Ann. § 17- 8-403(1)(d), creates liability for any person who "has possession, custody, or control of public property or money used or to be used by the governmental entity and knowingly delivers or causes to be delivered less than all of the property or money." Defendant has violated this provision of the Minnesota FCA.

205. The Montana FCA, Mont. Code Ann. § 17- 8-403(1)(g), creates liability for any person who "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 a governmental entity or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a governmental entity." Defendant has violated this provision of the Minnesota FCA.

206. Pursuant to the Montana FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Mont. Code Ann. § 17- 8-403(2).

Count XXI

Nevada False Claims Act
Nev. Rev. Stat. §§ 357.010, *et seq.*

207. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

208. This is a civil action brought by Relator, on behalf of the State of Nevada, against Defendant under the State of Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.080(1).

209. The Nevada FCA, Nev. Rev. Stat. § 357.040(l)(d), creates liability for any person who "[h]as possession, custody or control of public property or money and knowingly delivers or causes to be delivered to the State or a political subdivision less money or property than the

amount for which the person receives a receipt." Defendant has violated this provision of the Nevada FCA.

210. The Nevada FCA, Nev. Rev. Stat. § 357.040(l)(f), creates liability for any person who [k]nowingly makes or uses, or causes to be made or used, a false record or statement that is material to an obligation to pay or transmit money or property to the State or a political subdivision." Defendant has violated this provision of the Nevada FCA.

211. The Nevada FCA, Nev. Rev. Stat. § 357.040(l)(g), creates liability for any person who [k]knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State or a political subdivision." Defendant has violated this provision of the Nevada FCA.

212. Pursuant to the Nevada FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Nev. Rev. Stat. § 357.040(2).

Count XXII

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

213. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

214. This is a civil action brought by Relator, in the name of the State of New Jersey, against Defendant pursuant to the State of New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-5.b.

215. The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3.d., creates liability for any person who "[h]as possession, custody, or control of public property or money used or to be used by the State and knowingly delivers or causes to be delivered less property than the amount for

which the person receives a certificate or receipt." Defendant has violated this provision of the New Jersey FCA.

216. The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3.g., creates liability for any person who "[k]nowingly makes, uses, or causes 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 State." Defendant has violated this provision of the New Jersey FCA.

217. Pursuant to the New Jersey FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. N.J. Stat. Ann. § 2A:32C-3.

Count XXIII

New Mexico Medicaid False Claims Act
N.M. Stat. Ann. §§ 27-14-1, *et seq.*

218. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

219. This is a civil action brought by Relator, on behalf of the State of New Mexico, against Defendant under the State of New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-7.B.

220. The New Mexico FCA, N.M. Stat. Ann. § 27-14-4.E., creates liability for any person who "makes, uses or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the medicaid program, knowing that such record or statement is false." Defendant has violated this provision of the New Mexico FCA.

221. Pursuant to the New Mexico FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and such other relief as authorized. N.M. Stat. Ann. § 27-14-4.

Count XXIV

New York False Claims Act
N.Y. Fin. Law §§ 187, *et seq.*

222. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

223. This is a civil action brought by Relator, on behalf of the State of New York, against Defendant under the State of New York False Claims Act, N.Y. Fin. Law § 190(2).

224. The New York FCA, N.Y. Fin. Law § 189(1)(d), creates liability for any person who "has possession, custody, or control of property or money used, or to be used, by the state or a local government and knowingly delivers, or causes to be delivered, less than all of that money or property." Defendant has violated this provision of the New York FCA.

225. New York FCA, N.Y. Fin. Law § 189(1)(g), creates liability for any person who "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 state or a local government." Defendant has violated this provision of the New York FCA.

226. New York FCA, N.Y. Fin. Law § 189(1)(h), creates liability for any person who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a local government, or conspires to do the same." Defendant has violated this provision of the New York FCA.

227. Pursuant to the New York FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. N.Y. Fin. Law § 189(1).

Count XXV

North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-605, *et seq.*

228. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

229. This is a civil action brought by Relator, on behalf of the State of North Carolina, against Defendant under the State of North Carolina False Claims Act, N.C. Gen. Stat. § 1-608(b).

230. The North Carolina FCA, N.C. Gen. Stat. § 1-607(a)(4), creates liability for any person who "[h]as possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property." Defendant has violated this provision of the North Carolina FCA.

231. The North Carolina FCA, N.C. Gen. Stat. § 1-607(a)(7), creates liability for any person who "[k]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 State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State." Defendant has violated this provision of the North Carolina FCA.

232. Pursuant to the North Carolina FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. N.C. Gen. Stat. § 1-607(a).

Count XXVI

Oklahoma Medicaid False Claims Act
Okla. Stat. §§ 63-5053 (2007), *et seq.*

233. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

234. This is a civil action brought by Relator, in the name of the State of Oklahoma, against Defendant pursuant to the State of Oklahoma Medicaid False Claims Act, Okla. Stat § 63-5053.2(B).

235. The Oklahoma FCA, Okla. Stat § 63-053.1(B)(4), creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the state and, intending to defraud the state or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt." Defendant has violated this provision of the Oklahoma FCA.

236. The Oklahoma FCA, Okla. Stat § 63-053.1(B)(7), creates liability for any person who "[k]nowingly makes, uses, or causes 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 state." Defendant has violated this provision of the Oklahoma FCA.

237. Pursuant to the Oklahoma FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Okla. Stat. § 63-053.1(B).

Count XXVII

Puerto Rico False Claims Act
P.R. Laws Ann. Tit 32, § 2934, *et seq.*

238. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

239. This is a civil action brought by Relator, in the name of the Commonwealth of Puerto Rico, against Defendant under the False Claims to Government of Puerto Rico Programs, Contracts, and Services Act, P.R. Laws Ann. Tit. 32, § 2934a.

240. The Puerto Rico FCA, P.R. Laws Ann. Tit. 32, § 2934(1)(d), creates liability for any person who "[k]nowingly 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, relating to any Government Program or any service contract." Defendant has violated this provision of the Puerto Rico FCA.

241. Pursuant to the Puerto Rico FCA, Defendant is thus liable to the Commonwealth for statutorily defined damages sustained because of the acts of Defendant and civil penalties. P.R. Laws Ann. tit. 32, § 2934.

Count XXVIII

Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1-1, *et seq.*

242. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

243. This is a civil action brought by Relator, in the name of the State of Rhode Island, against Defendant pursuant to the State of Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-4(b).

244. The Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a)(4), creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the state and knowingly delivers, or causes to be delivered, less property than all of that money or property." Defendant has violated this provision of the Rhode Island FCA.

245. The Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a)(7), creates liability for any person who "[k]nowingly 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 state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state." Defendant has violated this provision of the Rhode Island FCA.

246. Pursuant to the Rhode Island FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. R.I. Gen. Laws § 9-1.1-3(a).

Count XXIX

Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 71-5-181, *et seq.*

247. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

248. This is a civil action brought by Relator, in the name of the State of Tennessee, against Defendant under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(b)(1) ("Tennessee FCA").

249. The Tennessee FCA, Tenn. Code Ann. § 71-5-182(a)(l)(D), creates liability for any person who "[k]nowingly 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 state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the medicaid program." Defendant has violated this provision of the Tennessee FCA.

250. Pursuant to the Tennessee FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Tenn. Code Ann. § 71-5-182(a).

Count XXX

Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code §§ 36.001, *et seq.*

251. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

252. This is a civil action brought by Relator, in the name of the State of Texas, against Defendant under the State of Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code § 36.101(a).

253. The Texas FCA, Tex. Hum. Res. Code § 36.002(12), creates liability for any person who "knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program." Defendant has violated this provision of the Texas FCA.

254. Pursuant to the Texas FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Tex. Hum. Res. Code § 36.052.

Count XXXI

Vermont False Claims Act
32 V.S.A. Chapter 7, Subchapter 8, *et seq.*

255. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

256. This is a civil action brought by Relator, in the name of the State of Vermont, against Defendant under the State of Vermont False Claims Act, 32 V.S.A. Chapter 7, Subchapter 8, § 632(b).

257. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(5), provides that no person shall "having possession, custody, or control of property or money used, or to be used, by the State, knowingly deliver, or cause to be delivered to the State or its agent, less than all of that property or money for which the person receives a certificate or receipt." Defendant has violated this provision of the Vermont FCA.

258. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(9), provides that no person shall "knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State." Defendant has violated this provision of the Vermont FCA.

259. The Vermont FCA, 32 V.S.A. Chapter 7, Subchapter 8, § 631(10), provides that no person shall "knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the State." Defendant has violated this provision of the Vermont FCA

260. Pursuant to the Vermont FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. 32 V.S.A. Chapter 7, Subchapter 8, § 631(b).

Count XXXII

Virginia Fraud Against Taxpayers Act
VA. Code Ann. §§ 8.01-216.1, *et seq.*

261. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

262. This is a civil action brought by Relator, on behalf of the Commonwealth of Virginia, against Defendant under the Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.5(A).

263. The Virginia FCA, Va. Code Ann. § 8.01-216.3(A)(4), creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the Commonwealth and knowingly delivers, or causes to be delivered, less than all such money or property." Defendant has violated this provision of the Virginia FCA.

264. The Virginia FCA, Va. Code Ann. § 8.01-216.3(A)(7), creates liability for any person who "[k]nowingly 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 Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth." Defendant has violated this provision of the Virginia FCA.

265. Pursuant to the Virginia FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Va. Code Ann. § 8.01-216.3(A).

Count XXXIII

Washington State Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.005, *et seq.*

266. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

267. This is a civil action brought by Relator, on behalf of the State of Washington, against Defendant under the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.050(1).

268. The Washington FCA, Wash. Rev. Code § 74.66.020(1)(d), creates liability for any person who "[h]as possession, custody, or control of property or money used, or to be used, by the government entity and knowingly delivers, or causes to be delivered, less than all of that money or property." Defendant has violated this provision of the Washington FCA.

269. The Washington FCA, Wash. Rev. Code § 74.66.020(1)(g), creates liability for any person who "[k]nowingly 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 entity, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government entity." Defendant has violated this provision of the Washington FCA.

270. Pursuant to the Washington FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Wash. Rev. Code § 74.66.020(1).

Count XXXIV

Wisconsin False Claims for Medical Assistance Act
Wis. Stat. §§ 20.931, *et seq.*

271. Relator incorporates by reference the preceding paragraphs as though fully set forth herein.

272. This is a civil action brought by Relator, on behalf of the State of Wisconsin, against Defendant under the State of Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931(5)(a), for acts occurring prior to the non-retroactive repeal of that law effective July 14, 2015.

273. The Wisconsin FCA, Wis. Stat. § 20.931(2)(g), creates liability for any person who "[k]nowingly 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." Defendant has violated this provision of the Wisconsin FCA with respect to conduct prior to July 14, 2015.

274. Pursuant to the Wisconsin FCA, Defendant is thus liable to the State for statutorily defined damages sustained because of the acts of Defendant and civil penalties. Wis. Stat. § 20.931(2).

VIII. PRAYERS FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendant as follows:

A. That Defendant be enjoined from using incorrect baseline data (including incorrect base AMP) and underreporting and underpaying the rebates due to the government for the drug Acthar in connection with the Medicaid Drug Rebate Program;

B. That judgment be entered against Defendant and in favor of the United States and the Relator in an amount equal to three times the amount of damages caused by Defendant's misconduct, as well as a civil penalty for each FCA violation in the maximum statutory amount;

C. That judgment be entered against Defendant and in favor of the *Qui Tam* States and the Relator in the amount of the damages sustained by the *Qui Tam* States multiplied as provided for in the State FCAs, plus civil penalties in the maximum statutory amount provided by the State FCAs;

D. That Defendant be ordered to disgorge all sums by which it has been enriched unjustly by its wrongful conduct;

E. That Defendant be ordered to accurately report accurate baseline data (including base date AMP) for Acthar in the Drug Data Reporting system for Medicaid and correctly pay rebates to the MDR Program in the future;

F. That judgment be granted for Relator against Defendant for all costs, including, but not limited to, court costs, litigation costs, expert fees, and all attorneys' fees permitted under the Federal FCA, 31 U.S.C. § 3730(d), and comparable provisions of the State FCAs;

G. That Relator be awarded the maximum amount permitted under the Federal FCA, 31 U.S.C. § 3730(d), and comparable provisions of the State FCAs; and

H. That the Court award such other relief as the Court deems proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff-Relator requests a jury trial.

March 2, 2020

Respectfully submitted,

/s/ Suzanne E. Durrell
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