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