

**UNITED STATES DISTRICT COURT
FOR THE 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,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt)
ARD, Inc.; f/k/a Questcor Pharmaceuticals, Inc.),)

Defendant.

Civil Action No. 18-11931-PBS

STATES' COMPLAINT IN INTERVENTION

Plaintiffs, the States/Commonwealths of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, the District of Columbia, and Puerto Rico (hereinafter, the "Plaintiff States") bring this action under their respective False

Claims Acts and state laws against Defendant Mallinckrodt ARD LLC (f/k/a Mallinckrodt ARD, Inc.; f/k/a Questcor Pharmaceuticals, Inc.) (hereinafter “Mallinckrodt”).

INTRODUCTION

The Plaintiff States bring this civil enforcement action brought pursuant to their respective False Claims Acts and other state laws to recover civil remedies, treble damages, civil penalties, and other relief against Mallinckrodt, a global specialty pharmaceutical company. The Plaintiff States allege that Mallinckrodt failed to report and return hundreds of millions of dollars in overpayments it possessed due to underpaying its obligations under the Medicaid Drug Rebate Program (“MDRP”) for Acthar Gel (“Acthar”).

Under the MDRP, when the manufacturer increases the price of a drug faster than the rate of inflation, it must pay the Medicaid program a per unit rebate of the difference between the drug’s current price and the price of the drug if its price had gone up at the general rate of inflation since 1990 (or when the drug first came to market, whichever is later). Acthar, which was first introduced to market in 1952 and is currently prescribed to treat numerous conditions including acute flares or relapses of multiple sclerosis, has increased in price far greater than the rate of inflation since 1990. Due to those increases, the rebate on Acthar *should* amount to nearly the entire cost of the drug. However, since 2013, Mallinckrodt has knowingly underpaid rebates owed from sales of Acthar under the MDRP—with the goal of retaining enormous profits—and as a result, illegally withheld hundreds of millions of dollars from the Medicaid program.

In 2012, Mallinckrodt, in an effort to increase profits realized through the sale of Acthar, misled the Centers for Medicare and Medicaid Services (“CMS”) regarding the approval history of Acthar. Mallinckrodt’s goal was to pay MDRP rebates as if Acthar was new to market in 2013 based on a new indication for Acthar approved by the Food and Drug Administration (“FDA”) in

2010. In actuality, Acthar had not changed in any meaningful way from the product first marketed in 1952. Mallinckrodt's misrepresentation about Acthar's approval history was financially motivated and was done in an effort to avoid the burdensome rebate obligations incurred as a result of Acthar's steep price increases.

By 2016, CMS became aware of the true nature of the FDA's 2010 approval and directed the company to return the overpayments Mallinckrodt had retained since 2013 and to pay future Medicaid rebates for Acthar based on all of the price increases for the drug since 1990. Rather than follow the directive, Mallinckrodt attempted to negotiate with the Federal Government and when rebuffed, filed an action pursuant to the Administrative Procedures Act, 5 U.S.C. §§ 700 *et seq.*, in the United States District Court for the District of Columbia, arguing that CMS was unlawfully demanding payment under an earlier approval date and increasing Mallinckrodt's obligations under the MDRP for sales of Acthar. The D.C. District Court granted summary judgment in favor of the government, finding that CMS lawfully determined that rebates should be paid according to Acthar's original approval date.¹

Mallinckrodt knowingly failed to fulfill its obligations under the MDRP with regard to Acthar since 2013. Accordingly, the Plaintiff States seek to recover hundreds of millions of dollars in rebates that Mallinckrodt has illegally withheld from the Medicaid program, civil remedies, treble damages, civil penalties, and all of the recoveries provided for in each of their respective state statutes and common law.²

¹ *Mallinckrodt ARD LLC v. Verma et al.*, __F.Supp.3d__, 2020 WL 1312716 (D.D.C. March 13, 2020).

² The Texas Supreme Court ruled that actions brought under the Texas Medicaid Fraud Prevention Act are not "damages" but are instead civil remedies. *See In re Xerox*, 555 S.W.3d 518, 526-535 (Tex. 2018) (discussing the relevant provision under the heading "The Remedies in section 36.052 Are Not Damages").

JURISDICTION AND VENUE

1. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (“FCA”). In addition, the FCA specifically confers jurisdiction upon the United States District Court. 31 U.S.C. § 3732(b).

2. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought by the Plaintiff States on the grounds that those claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

3. This Court may exercise personal jurisdiction over Mallinckrodt pursuant to 31 U.S.C. § 3732(a), and because Mallinckrodt transacts business in this District.

4. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. §§ 1391(b)-(c) because Mallinckrodt transacts business in this District.

PARTIES

5. The Plaintiff States bring this action on behalf of their respective Medicaid programs and on behalf of their respective State interests.

6. Relator James Landolt is an individual who resides in the State of Minnesota.

7. Defendant Mallinckrodt ARD LLC (f/k/a Mallinckrodt ARD, Inc.; f/k/a Questcor Pharmaceuticals, Inc.), a subsidiary of Mallinckrodt plc, an Irish public limited company, is a California limited liability company with its principal place of business at 1425 U.S. Route 2015, Bedminster, NJ 07921.

8. Mallinckrodt marketed Acthar throughout the United States at all relevant times for purposes of this complaint in intervention. Since 2013, Mallinckrodt knowingly underpaid rebates on Acthar to the Plaintiff States' Medicaid programs.

LEGAL FRAMEWORK

THE MEDICAID PROGRAM

9. The Medicaid Program is authorized by Title XIX of the Social Security Act and Title 42 of the Code of Federal Regulations. Medicaid is a joint federal-state program that provides health care benefits, including prescription drug coverage, for certain groups including the poor and disabled. The funding for Medicaid is shared between the federal and state governments. Each state's Medicaid program is required to implement a State Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. §1396a. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b).

THE MEDICAID DRUG REBATE PROGRAM

10. The Medicaid Drug Rebate Program was enacted in an effort to protect Medicaid from increasing prescription drug prices. Specifically, Congress determined that Medicaid regularly paid more than other large drug purchasers for prescription drugs, particularly for "single source" or "branded" drugs (*e.g.*, Acthar). *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. The Medicaid Drug Rebate Statute ("Rebate Statute"), 42 U.S.C. § 1396r-8, states that in order for a drug manufacturer's drugs to be eligible for Medicaid

reimbursement, the manufacturer must enter into a Rebate Agreement. 42 U.S.C. § 1396r-8(a)(1). The terms of the Rebate Agreement are laid out in the Rebate Statute. Since 1991, the nationwide template Rebate Agreement, or “National Drug Rebate Agreement” (“NDRA”) has been published in the Federal Register. *See* Medicaid Program, Drug Rebate Agreement, 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991). The NDRA was last updated in 2018. *See* Medicaid Program, Announcement of Medicaid Drug Rebate Program National Rebate Agreement, 83 Fed. Reg. 12770, 12784 (Mar. 23, 2018). Acthar has been covered under a rebate agreement since at least 2002. [Exhibits 1-5.]

11. The Rebate Statute and NDRA both require manufacturers to pay each state Medicaid program a quarterly rebate per unit of each “dosage form and strength” of a “covered outpatient drug,”³ purchased by Medicaid during that quarter. 42 U.S.C. § 1396r-8(c). Payment is due within 30 days of each state reporting to the manufacturer the quantity of each dosage form and strength and package size of each covered outpatient drug dispensed and payment that was made by the state Medicaid program that quarter. 42 U.S.C. §§ 1396r-8(b)(1), (2).

12. There are different rebate calculation formulas for different categories of “covered outpatient drugs.” These drugs fall into three categories: “single source,” “innovator multiple source,” or “non-innovator multiple source” drugs. 42 U.S.C. § 1396r-8(k)(7).

13. “Single source” drugs, or brand name drugs without generic equivalents, are generally subject to the highest rebate obligations. A “single source” drug is a “covered outpatient drug” that is produced or distributed under a New Drug Application (“NDA”) approved by the FDA. 42 U.S.C. § 1396r-8(k)(7)(A)(iv).⁴

³ The Rebate Statute defines “covered outpatient drug,” in pertinent part, to mean “a drug . . . which is approved for safety and effectiveness as a prescription drug” under section 505 of the Food Drug and Cosmetic Act, 21 U.S.C. § 355(b). 42 U.S.C. § 1396r-8(k)(2).

⁴ The statute previously defined a “single source” drug as a “covered outpatient drug” “produced or distributed under an *original* NDA approved by the FDA.” 42 U.S.C. § 1396r-8(k)(7)(A)(iv) (2018) (emphasis added).

14. In an effort to protect the Medicaid program from drug prices that rise faster than the rate of inflation, like Acthar's, the Rebate Statute requires manufacturers to pay an "additional rebate." 42 U.S.C. § 1396r-8(c)(2). For drugs approved by the FDA and marketed on or before July 1, 1990, such as Acthar, the Rebate Statute requires manufacturers to calculate and pay this rebate by: 1) adjusting the drug's third quarter 1990 average manufacturer price ("AMP") for inflation since that time; 2) comparing the drug's inflation-adjusted 1990 AMP to the drug's actual current AMP; and 3) if the current AMP is higher than the inflation-adjusted 1990 AMP, paying the difference for each unit that a state Medicaid program purchased. 42 U.S.C. § 1396r-8(c)(2)(A).⁵ The requirements for this additional rebate are as follows:

- (A) **The amount of the rebate** specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, **shall be increased by an amount equal to the product of—**
 - (i) **the total number of units of such dosage form and strength** dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; **and**
 - (ii) **the amount (if any) by which—**
 - (I) **the average manufacturer price for the dosage form and strength of the drug** for the period, **exceeds**
 - (II) **the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990** (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), **increased by** the percentage by which **the consumer price index** for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

Id. ("Additional rebate for single source and innovator multiple source drugs") (emphasis added).

⁵ While there are other types of rebates, the instant action only deals with this "additional rebate."

15. The same formula applies for covered outpatient drugs first marketed after July 1, 1990; however, the manufacturer uses the first full quarter after market introduction rather than the third quarter of 1990 as the basis for determining the additional rebate. 42 U.S.C. § 1396r-8(c)(2)(B). The Rebate Statute reads in pertinent part:

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of **subparagraph (A) shall be applied by substituting “the first full calendar quarter after the day on which the drug was first marketed”** for “the calendar quarter beginning July 1, 1990” and “the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed” for “September 1990”.

Id. (“Treatment of subsequently approved drugs”) (emphasis added).

16. In general, the starting AMP for the inflation-based comparison is referred to as the “Base Date AMP.” *See, e.g.*, NDRA, 83 Fed. Reg. at 12784, § I(c) (“‘Base Date AMP’ will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the [Social Security] Act.”).

17. In the event a single source drug’s price increase outpaces the rate of inflation, like Acthar’s, the “additional rebate” owed could be substantial, however, the total rebate owed “with respect to each dosage form and strength of a single source drug” is capped at “100 percent of the [AMP] of the drug.” 42 U.S.C. § 1396r-8(c)(2)(D).

18. Manufacturers are required to make quarterly reports to CMS with certain pricing information, including AMP, for each drug through CMS’s Drug Data Reporting (“DDR”) system. *See* 42 U.S.C. § 1396r-8(b)(3). Manufacturers report a drug’s Base Date AMP to CMS at the outset of that drug entering the MDRP. All submissions through the DDR are certified as accurate by the manufacturer.

19. Manufacturers are responsible for calculating and paying the proper rebates owed for each of their drugs. Notwithstanding that responsibility, CMS takes the information reported

by the manufacturer through the DDR and applies the Rebate Statute formula to determine a “Unit Rebate Amount” (“URA”) for each drug. *See* NDRA at § I(aa), 83 Fed. Reg. at 12784 (“[URA] means the computed amount to which the state drug utilization data is applied by states in invoicing the manufacturer for the rebate payment due.”). While CMS calculates and provides URAs to the states, which invoice the manufacturers, manufacturers have an independent obligation to pay the proper rebate amounts. 42 U.S.C. § 1396r-8(b)(1)(A) (“[A] rebate . . . in an amount specified in [42 U.S.C. § 1396r-8(c)] . . . shall be paid by the manufacturer not later than 30 days after the receipt of” utilization information from the states); NDRA at § II(b), 83 Fed. Reg. at 12785 (“CMS’s URA calculation does not relieve the manufacturer of its responsibility to calculate the URA.”).

20. “To the extent that changes in product, pricing, or related data cause increases to previously submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30-day time frame as the current rebate invoice.” NDRA at § II(f), 83 Fed. Reg. at 12785.

THE FDA APPROVAL PROCESS

21. When a company seeks to market and sell a new medical product in the United States, including pharmaceutical drugs, they submit an NDA to the FDA. NDAs are “stand-alone” applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.3(b). The FDA assigns each NDA submitted for a pharmaceutical drug a six-digit NDA number that is unique to that submission.

22. Manufacturers are permitted to assign several different National Drug Code (“NDC”) numbers to a drug approved under a single NDA. The NDC number usually consists of

eleven-digits, containing the manufacturer's labeler code, the product code, and the package code. *See* 21 C.F.R. § 207.33. Therefore, multiple NDCs does not indicate the drug has changed.

23. Once approved, manufacturers can propose subsequent changes to the drug or its labeling through the Supplemental New Drug Application ("sNDA") process. *See* 21 C.F.R. §§ 314.70–71. Manufacturers can submit sNDAs to seek additional "indications"—an FDA-approved use that permits a manufacturer to market the drug as safe and effective for treating that condition—when the drug product itself remains the same. After an NDA is approved, any requests to add or modify indications should be submitted individually in a separate supplement to an approved original application. FDA Guidance for Industry Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), *available at* <https://www.fda.gov/media/72397/download> (last visited 7/01/2020). These supplements are known as "efficacy supplements." 21 C.F.R. § 314.3(b). Each supplement is sequentially numbered, but the original NDA remains the same. *See* Drugs@FDA Glossary of Terms, <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#S> (last visited 07/01/2020).

24. Until mid-2009, when a sNDA for a new indication needed to be reviewed by an FDA division other than the division that reviewed and approved the initial NDA, the FDA created a "Type 6 NDA," with an associated tracking number. Type 6 NDAs were assigned when the drug itself had already been approved and marketed, but a new indication or claim was being sought. FDA NDA Classification Manual at 5, *available at* <https://www.fda.gov/media/94381/download> (last visited 07/01/2020). Because Type 6 NDAs had only an administrative function, the FDA closed Type 6 NDAs upon approval.

STATEMENT OF FACTS

25. The instant complaint is based upon the same factual allegations as the complaint filed by the United States in this matter. For this reason, the Plaintiff States hereby incorporate by reference and adopt paragraphs 32 through 93 of the Complaint of the United States, with the exception of paragraph 87, as if fully alleged and set forth herein.

Initial Approval of Acthar in 1952 and Approval of Efficacy Supplement for Infantile Spasms in 2010

26. In 1952, Acthar was approved under NDA 008372. Since then, Acthar, under NDA 008372, has been supplemented often and now has nearly twenty indications.

27. In 2001, Questcor acquired Acthar. Questcor submitted an sNDA, identified as “sNDA 08-372/S-039,” for NDA 008372 in 2006. This sNDA was for an additional indication for infantile spasms, a seizure disorder affecting young children.

28. On August 8, 2008, after receiving the sNDA and beginning the review process, the FDA sent Questcor an e-mail indicating that the FDA “created a separate NDA number for your infantile spasm submission **for administrative purposes,**” and that “[t]he new number is NDA 22-432.” [Exhibit 6.] (Emphasis added.)

29. The administrative nature of this “separate NDA” is further documented in an FDA internal memo dated August 8, 2008, which stated that the Type 6 NDA number was assigned so that the supplemental indication application could be reviewed by the proper FDA division. [Exhibit 7.] Despite providing a “new NDA” to the submission, the FDA’s internal correspondence throughout the approval process further demonstrated it considered this application to be a supplement to the approval received in 1952. [Exhibits 8, 9, and 10.]

30. Finally, in the FDA's 2010 letter approving the infantile spasms indication, the FDA emphasized the temporary, administrative nature of NDA number 022432, when the letter concluded by directing Questcor to no longer use that NDA:

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original **NDA 008372** for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

[Exhibit 11 at 5.] (Emphasis in original.)

31. In addition to filing a sNDA, which has obvious implications, Questcor's subsequent filings also establish that it knew that its 2006 application was supplemental to an existing drug. On November 2, 2010, Questcor filed a Form 10-Q with the Securities and Exchange Commission, in which it referred to the approval of its "**supplemental** New Drug Application, or **sNDA**, for Acthar for the treatment of IS." Questcor, SEC Form 10-Q at 15 (Nov. 2, 2010) (emphasis added), *available at* <https://www.sec.gov/Archives/edgar/data/891288/000119312510242905/d10q.htm> (last visited 07/01/2020). Additionally, Questcor touted the approval of a **supplemental** NDA in its press release. *See* Press Release, *FDA Approves H.P. Acthar® Gel for the Treatment of Infantile Spasms* (Oct. 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> (last visited 07/01/2020).

32. There are numerous additional examples of the FDA and Questcor's shared knowledge that a supplemental NDA was approved in 2010, and not a new NDA for a new drug product:

- In a March 5, 2011, application for a labeling supplement, Questcor characterized 22432 as a "tracking NDA." [Exhibit 12.]

- Similarly, on May 3, 2011, in a letter to the FDA regarding Acthar's label, Questcor wrote that "[t]he **efficacy supplement** for Treatment of Infantile Spasms was approved under **the tracking NDA number 22,432** on October 15, 2010." [Exhibit 13.] (Emphasis added.) In that letter, Questcor recognized that, "**since the tracking NDA number [22432] will no longer be used**, we are submitting this Changes Being Effectuated Labeling Supplement to the **parent NDA 08,372**." [Id.] (Emphasis added.)
- In approving an additional supplement, the FDA reiterated that "the indication for the treatment of infantile spasms [is] to be associated with the parent NDA number 008372, **since the tracking NDA number 022432 will no longer be used**." [Exhibit 14.] (Emphasis added)

33. Mallinckrodt subsequently acquired Acthar in 2014 when it purchased Questcor Pharmaceuticals.

34. Mallinckrodt acknowledged as recently as February 2020 that the approval in 2010 was for a supplemental NDA for the infantile spasms indication. Mallinckrodt, SEC Form 10-K at 29 (Feb. 26, 2020) (emphasis added), *available at* <https://mallinckrodt.gcs-web.com/static-files/1252745e-320c-4090-b92f-b3cc14b6bc3f> (last visited 07/01/2020).

35. The FDA publishes a list of marketed drug products, referred to as the "Orange Book." The only NDA listed for Acthar in the FDA Orange Book is the original NDA, 008372. *See* FDA Orange Book listing for Acthar, *available at* https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=008372#17292 (last visited 07/01/2020). Neither the online version nor the print version of the Orange Book lists any drug associated with NDA number 022432, because the FDA has not approved a drug for marketing under that tracking NDA number. Also telling, Acthar's approved label still lists its initial approval date as 1952.

Efforts to Avoid Rebate Payments Owed Due to Acthar's Price Increases

36. Throughout the 2000s, Questcor raised the price of Acthar much faster than the rate of inflation.⁶ The ascent of Acthar's price was so much steeper than the rate of inflation, that Questcor owed the maximum allowable rebate, or 100% of Acthar's AMP, in any given quarter. Questcor paid this amount, using the 1990 Base Date Amp, until 2013.

37. Despite making proper payments until 2013, Questcor looked to solve this self-created problem as early as 2011. Rather than lowering the price of Acthar, which also could have reduced the rebates owed, Questcor instead sought to lower its rebate obligations while maximizing profits. Questcor tried to convince CMS to arbitrarily reset Acthar's Base Date AMP during a March 2012 meeting, stating that CMS could agree to the new Baseline AMP based on the 2010 sNDA approval or accept Questcor's termination of MDRP participation, in which Medicaid would still be required to cover the drug, but would not receive a rebate. [Exhibit 15.]

38. In May 2012, Questcor wrote to CMS, reiterating its threat to leave the MDRP if CMS did not permit the company to set a new Base Date AMP for Acthar. To support its argument, Questcor stated that Acthar had been approved in 2010 under a new NDA. Questcor wrote that the FDA "approved Acthar under NDA 22-432 for treatment of infantile spasms on October 15, 2010" and, separately, that "[o]n October 15, 2010, Acthar was approved to treat infantile spasms under NDA 22-432." Rather than properly characterizing the 2010 approval as an efficacy supplement, or follow the FDA's directive that it was to not use NDA 22-432 any further, Questcor instead disclosed in a footnote in its letter that "Acthar's original NDA is number 08-372, and the FDA has informed Questcor that the agency intends to revise its record so that the approval for infantile

⁶ Questcor's May 2012 letter describes an Acthar price increase from \$1,650 to \$23,269 per vial in August 2007. [Exhibit 16 at 4.]

spasms is reflected as part of the product's original NDA, No. 08-372. That has not yet occurred.”
[Exhibit 16 at 3.]

39. Questcor knew that it did not have a valid basis for its request to CMS to reset the Base Date AMP. In a May 2012 e-mail to Questcor's Board of Directors, Questcor's CEO wrote: “Keep your fingers crossed. Our probability is still low here, but non-zero.” [Exhibit 17 at 1.]

40. Questcor failed to disclose key facts that it knew about the 2010 approval in its March 2012 meeting and May 2012 letter. Questcor failed to disclose that the 2010 approval was precipitated by its filing of an sNDA. Questcor failed to disclose that the 2010 approval of the infantile spasms indication was an efficacy supplement. Similarly, Questcor never disclosed to CMS that it knew that NDA number 22-432 was a tracking number assigned for administrative purposes. It also never disclosed that the FDA already had directed Questcor not to make future submissions to this “tracking” NDA number (but instead to use the 1952 “parent NDA”) and that Questcor already had taken steps with the FDA to merge the infantile spasms approval into the label for the 1952 “parent NDA.”

41. Not only did Questcor fail to make the appropriate disclosures about tracking NDA number 22-432, it attempted to make the 2010 supplement appear to be more than just a label revision to add a new indication. Questcor discussed the FDA's review of Acthar's safety and efficacy for infantile spasms, noting that the FDA required a new indication-specific “Risk Evaluation and Mitigation Strategy” and concluded that product was safe and effective after reviewing the data. Questcor represented that the 2010 approval “represent[s] a significant revision in the product's labeling and in the conditions under which it will be marketed and distributed.” [Exhibit 16 at 4.]

42. On August 6, 2012, CMS issued a letter stating that Acthar is eligible for a new Base Date AMP “given that the recently approved Acthar Gel was approved under a different [NDA] from the original product.” [Exhibit 18 at 1.] CMS reasoned, “the base date AMP is calculated based on the new drug application which is approved by the FDA.” It further cautioned that CMS “does not have the current capability to allow a manufacturer to replace the original reported base date AMP with a new base date AMP midway through the life of a product.” In a September 19, 2012, follow-up letter correcting a typographical error, CMS again cited Questcor’s misrepresentation that “because Acthar was approved under a new NDA, Questcor may set a new [Base Date AMP].” [Exhibit 19 at 1.] Both the August and September letters stated that the decision was based on Questcor’s representation that the 2010 efficacy supplement approval was actually for a new product. Both letters were equally clear that CMS’ decision was limited and based on the facts and information presented to CMS.

43. Instead of clarifying CMS’s clear misunderstanding of the 2010 approval, Questcor accepted its windfall, and in January 2013, reported a new NDC for Acthar to CMS’s DDR system, and additionally reported a new Base Date AMP. Despite the fact that Acthar has remained unchanged since it was first approved in 1952, starting in 2013, Questcor paid rebates for Acthar as if the drug were just being introduced to market. Internal emails between Questcor executives in 2012 estimated that the change in Base Date AMP would result in over \$60,000,000 in added revenues *per year* resulting from their payment of artificially reduced rebates. The CEO further noted, “[s]ince there are no offsetting costs except bonuses, most of this falls to the op income line.” [Exhibit 20.]

44. Even prior to its March 2012 meeting with CMS, Questcor appreciated how vastly its financial position would improve if it could reduce its rebate obligations. It analyzed the impact

of the rebate on the company's profitability, and asserted in its March 2012 meeting that its 2011 Medicaid rebate liability was estimated to be \$47 million (amounting to "approximately 17% of total company sales") and asserted in its May 2012 letter that the "rebate liability for the product exceeds the Medicaid payments for the drug," resulting in "negative revenue" for Questcor. [Exhibit 16.] As noted in an email from Questcor's CEO to its board, for years, Questcor had been trying to "improve [its] Medicaid rebate situation," beginning in 2009 with "penetrat[ing] the legislative process" through lobbying to change the Rebate Statute, and later hiring law firms to consider "many ways" that it may reduce its Medicaid rebates. [Exhibit 17 at 1.]

45. In 2016, CMS realized the true nature of the 2010 approval, and sent a letter to Mallinckrodt on April 13, 2016, informing Mallinckrodt that despite a new NDC, Acthar was the same drug, and was marketed under the same NDA as the drug with the prior NDC. CMS went on to quote the October 15, 2010 FDA approval letter, which clearly directed that NDA 022432 no longer be used, in favor of NDA 008372. CMS then instructed Mallinckrodt to make the "necessary correction." [Exhibit 21 at 1.]

46. Days after CMS sent the April 13, 2016 letter, internal emails show that Mallinckrodt estimated that complying with CMS's directive would result in a 223% increase in Acthar rebates for the first quarter of 2016. [Exhibit 22.] There are also internal emails from Mallinckrodt's Regulatory Affairs department that demonstrate knowledge that NDA 022432 was temporary and would be merged into the existing NDA. [Exhibit 23.] Specifically, a senior director in the Regulatory Affairs department advised that "[NDA] 008372 is the approved Acthar application that is pertinent. We are working with FDA to roll the information from NDA 022432, which was supposed to be a temporary NDA tracking number for the Infantile Spasms approval, into NDA 008372." [Exhibit 23.] (Emphasis added.) A project manager in Mallinckrodt's Finance

Group then asked if NDA 008372 would be “the final NDC and the FDA approval date will be 04/29/1952,” to which the Regulatory Affairs senior director responded, “Correct.” [Exhibit 23.]

47. Despite Mallinckrodt’s own Regulatory Affairs department agreeing with CMS’s interpretation, Mallinckrodt continued to shirk its responsibility under the MDRP. On May 10, 2016, Mallinckrodt responded to CMS by attaching Questcor’s May 2012 letter to CMS and CMS’s August 2012 response. In the accompanying cover e-mail, Mallinckrodt wrote: “Attached please find correspondence between Questcor/Mallinckrodt and CMS regarding the approved NDC changes and new base AMP for Acthar. Please advise if we are required to make any changes to the DDR.” [Exhibit 24 at 4.]

48. On June 2, 2016, CMS replied to Mallinckrodt’s May 10, 2016, e-mail. CMS made clear that despite the 2012 correspondence with Questcor and despite the new NDC, Acthar had been on the market unchanged since 1952. CMS wrote, in pertinent part:

We are aware of the correspondence between Questcor and CMS that you provided. However, as stated in [CMS-issued guidance Manufacturer Release 90] the baseline data of a purchased product should be the same as the baseline data of a product marketed previously under the same NDA. **Therefore, we are requesting that you complete and return the attached template 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.**

[Exhibit 24 at 3-4.] (Emphasis added.)

49. Approximately two weeks after receipt of that email from CMS, a detailed spreadsheet was circulated from Mallinckrodt’s Government Reporting department to high-level executives estimating that Mallinckrodt would owe over \$258,000,000 in retroactive rebates under the MDRP were it to comply the CMS’s directive to reset Acthar’s Base Date AMP. [Exhibit 25.]

50. Rather than concede and take corrective action to address their underpayments to the Medicaid program, Mallinckrodt continued to defy its Regulatory Affairs department’s

position, and attempted to convince CMS not to reset its Base Date AMP. In a July 6, 2016, email from Mallinckrodt to CMS, Mallinckrodt repeated its misrepresentation as to the circumstances surrounding the infantile spasms indication approval in 2010. Mallinckrodt continued to represent Acthar with the infantile spasms indication as a new drug product. It characterized the 2010 approval of NDA 022432 as approving “the product that was discussed in the CMS letter of August 6, 2012,” suggesting that this “product” was different from the Acthar originally approved in 1952. [Exhibit 24 at 3.]

51. On March 20, 2017, CMS sent Mallinckrodt another email reiterating that the provision of the 2010 administrative tracking NDA was not sufficient to support its use of a 2013 Base Date AMP. CMS’s email read:

Thank you for your emails on July 6, 2016 and July 29, 2016. We understand and agree that the new indication for Acthar was approved under NDA 022432. We also note that the SPL information submitted to FDA by the manufacturer currently reflects NDA 022432. However FDA has confirmed that **NDA 022432**, a type-6 NDA, was **created for administrative purposes** because an FDA division other than the division responsible for NDA 008372 was reviewing the application for the new indication. FDA has informed us that type-6 NDAs are administratively closed upon approval. **Therefore, it is our understanding that the marketing of the drug has always been under the auspices of NDA 008372, regardless of the administratively assigned NDA 022432, which was only for the purpose of FDA approval of the new indication, but not for the approval and marketing of the drug itself.**

The baseline information for a drug that was approved prior to the effective date of section 1927 of the Social Security Act is established using the data of the drug as of 9/30/1990. **It is our understanding that 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.**

[Id. at 2-3.] (Emphasis added.)

52. On April 14, 2017, Mallinckrodt responded to the email by contending that the agency’s decision to allow it to use a new Base Date AMP was and is correct because the approval

of “NDA 022432” was significant in that the infantile spasms indication was added and several indications were removed. As Mallinckrodt did in concluding its July 6, 2016 email, it intimated that it would continue to review CMS’s position and may follow-up. [Exhibit 26.] Mirroring the events following the July 2016 email, Mallinckrodt never followed-up with CMS and continued to underpay rebates.

53. On November 6, 2018, with Mallinckrodt continuing to underpay rebates in defiance of CMS’s warnings and directives, CMS sent yet another letter to Mallinckrodt, which read in part:

On April 13, 2016 and March 20, 2017 CMS informed Mallinckrodt LLC that it was reporting incorrect base Average Manufacturer Price (base AMP) information and an incorrect FDA application number in the Drug Data Reporting for Medicaid (DDR) system. This is a notice that Mallinckrodt LLC has not taken action to date to correct this information and must do so within 30 days of receiving this notice and notify CMS of its action, otherwise CMS will identify the following national drug code (NDC) as “out of compliance” in the DDR system as of December 17, 2018.

CMS further informed Mallinckrodt that it was responsible for repaying the state Medicaid programs the amounts previously underpaid on Acthar rebates. In response, Mallinckrodt repeated its prior arguments and asked for additional time. [Exhibit 26 at 3.]

54. On January 18, 2019, the Department of Justice, having received the instant *qui tam* action, served Mallinckrodt a Civil Investigative Demand for documents concerning Acthar’s Base Date AMP.

55. On March 7, 2019, CMS and Mallinckrodt had an in-person meeting, after Mallinckrodt requested a postponement of an earlier-scheduled meeting. A few days later, on March 11, 2019, Mallinckrodt’s attorney sent CMS a letter advising that it would like an additional meeting and requesting a delay in enforcement.

56. The following day, CMS responded:

As we have said in our prior communications of April 13, 2016, June 2, 2016, and March 20, 2017, and as we reiterated at the March 7th meeting, the base date AMP of H.P. Acthar Gel should reflect the base date AMP for the drug that was first produced or distributed under new drug application (NDA) 008372. Because H.P. Acthar gel is currently, and always has been, produced or distributed under NDA 008372, the base date AMP Mallinckrodt is reporting to the Drug Data Reporting for Medicaid (DDR) system does not reflect the appropriate base date AMP, and **Mallinckrodt has been underpaying Medicaid rebates for H.P. Acthar Gel.**

[Exhibit 27 at 2.] (emphasis added)

57. Rather than taking any corrective action or actually following up with CMS, Mallinckrodt contacted the general counsel for the Department of Health and Human Services and requested a meeting. On March 27, 2019, HHS general counsel rebuffed that request, and advised that the April 13, 2016 letter from CMS constituted a final decision.

58. Seemingly out of options, on April 12, 2019, Mallinckrodt offered to change Acthar's Base Date AMP back to 1990 on a prospective basis in exchange for CMS acknowledging that "Mallinckrodt's use of Acthar's post-2012 base date AMP was appropriate." CMS declined this proposal.

59. On May 10, 2019, the agency sent Mallinckrodt a letter giving the company 14 days to correct Acthar's Base Date AMP to the 1990 price:

As we noted in our latest March 12, 2019 letter to Mallinckrodt, the current base date AMP that you are reporting to the Drug Data Reporting (DDR) for Medicaid system does not reflect the appropriate base date AMP for H.P. Acthar Gel. In that letter, we provided you with a template that we asked you to return to us so we can make the change in DDR so Mallinckrodt can report the appropriate base date AMP and ensure the appropriate rebate payments. To date, the company has not returned the template.

...

As we have discussed, the April 13, 2016 letter sent to the [sic] Mallinckrodt regarding this issue constituted the agency's final decision on this issue, and any further discussions regarding this issue would not be productive. **Accordingly, we are not entertaining the proposal included in your April 12, 2019**

correspondence and reiterate that you must take action within 14 days to submit the corrected information.

[Exhibit 28 at 2.] (Emphasis added.)

60. On May 20, 2019, instead of correcting Acthar's Base Date AMP or taking any measures to repay rebates owed, Mallinckrodt filed a lawsuit in the United States District Court for the District of Columbia seeking to enjoin CMS from taking any action to enforce its determination that Acthar has a 1990 Base Date AMP. In filing that lawsuit, Mallinckrodt did not disclose that its conduct was already the subject of a Department of Justice investigation or that its lawsuit was unsupported by its own regulatory department who agreed with CMS.

61. On March 2, 2020, the United States intervened in this matter and its complaint-in-intervention was filed the next day.

62. On March 13, 2020, the United States District Court for the District of Columbia granted CMS's Motion for Summary Judgment and directed the Clerk to enter judgment on behalf of the Government. Notably, the court found that CMS lawfully determined that the Rebate Statute requires that Acthar's Base Date AMP be calculated based on the date the drug was approved by the FDA under NDA 008372 in 1952, so that Mallinckrodt should have paid rebates based on its 1990 Base Date AMP. *Mallinckrodt ARD LLC v. Verma*, --- F.Supp.3d ----, 2020 WL 1312716 (D.D.C. March 13, 2020).

63. Based on its review of the administrative record, the court noted that when CMS authorized a new Base Date AMP in 2012, it was clearly laboring under the erroneous assumption that the new NDA 022432 accompanied approval of a new drug product and that CMS put Questcor "on notice" that CMS was relying on that assumption. *Id.* at *19. Since Mallinckrodt knew that NDA 022432 was not associated with approval of a new drug product, the court reasoned, "it would have behooved the companies [Mallinckrodt and Questcor] to clarify the

agency's understanding.” *Id.* at *18. And, “[p]laced on notice of that erroneous assumption via CMS’s 2012 approval letter, Questcor (and later Mallinckrodt) gambled” by resetting Acthar’s AMP “without first clarifying this point, particularly in light of the statute’s clear language” about the relevant Base Date AMP. *Id.* at *19.

64. On June 1, 2020, Mallinckrodt filed its notice of appeal of the District Court for the District of Columbia’s ruling.

65. On June 2, 2020, Mallinckrodt sought an injunction pending appeal to prevent CMS from locking it out of the DDR if it did not update its Base Date AMP.

66. On June 15, 2020, the United States Court of Appeals for the D.C. Circuit denied Mallinckrodt’s request for an injunction.

THE ACTIONABLE CONDUCT OF MALLINCKRODT

67. Since January 1, 2013, Mallinckrodt has underpaid the “additional rebates” owed under the MDRP for Acthar, which it calculated using a 2013 Base Date AMP rather than the 1990 Base Date AMP it should have used. Mallinckrodt’s conduct has deprived the Plaintiff States of hundreds of millions of dollars, causing significant financial harm to the governments of each state and the federal government.

68. Due to the steep price increases on Acthar since 1990, the Rebate Statute required Mallinckrodt to pay Medicaid rebates based upon a URA equaling 100 percent of Acthar’s AMP every quarter. However, because Mallinckrodt misled CMS and paid rebates as if Acthar was a new drug first marketed in 2013, they paid rebates on a much lower URA.

69. For each calendar quarter invoiced and paid through the fourth quarter of 2019,⁷ Mallinckrodt underpaid its Acthar MDRP rebates by between \$3,800 and \$4,400 *per unit*.⁸

70. Consequently, Mallinckrodt significantly underpaid its rebate obligation for each and every unit of Acthar reimbursed by Medicaid. Due to the extremely high price of Acthar, and because Medicaid has reimbursed a large volume of Acthar, Mallinckrodt has deprived the States' Medicaid programs collectively of hundreds of millions of dollars in rebates.

71. Mallinckrodt's payment of artificially low rebates for Acthar has caused the Plaintiff States to incur greater costs to operate their Medicaid programs and has harmed the state governments.

72. The Medicaid programs of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, the District of Columbia, and Puerto Rico each paid reimbursements for Acthar Gel in calendar quarters between January 2013 to March 2020, such that Mallinckrodt owed and underpaid a rebate to the Medicaid program of each Plaintiff State during that seven-year period.

⁷ Data for the first quarter of 2020 was unavailable at the time of drafting this complaint.

⁸ This range has been included instead of the exact per unit dollar amounts of quarterly underpayments. While the difference between the correct URA and the paid URA would not be confidential, the difference is premised on underlying information that is confidential. Accordingly, the States have opted to use this range in abundance of caution. Should the Court feel the exact amounts are necessary to meet the requirements of Rule 9(b), the information can be provided for *in camera* inspection.

CAUSES OF ACTION

CLAIMS OF THE STATE OF ALASKA

Count I – Reverse False Claims

(Alaska Medical Assistance False Claim and Reporting Act, AS 09.58.010, *et seq.*)

73. The State of Alaska re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

74. The Alaska Medical Assistance False Claim and Reporting Act, AS 09.58.010 provides, in pertinent part, that:

- (a) a medical assistance provider or medical assistance recipient may not
 - (1) knowingly submit, authorize, or cause to be submitted to an officer or employee of the state a false or fraudulent claim for payment or approval under the medical assistance program;
 - (2) knowingly make, use, or cause to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim for payment paid or approved by the state under the medical assistance program;
 - (4) knowingly make, use, or cause 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;
 - (5) knowingly enter into an agreement, contract, or understanding with an officer or employee of the state for approval or payment of a claim under the medical assistance program knowing that the information in the agreement, contract, or understanding is false or fraudulent.
- (c) In addition to any criminal penalties under AS 47.05, a medical assistance provider or medical assistance recipient who violates (a) or (b) of this section shall be liable to the state in a civil action for
 - (1) a civil penalty of not less than \$5,500 and not more than \$11,000;
 - (2) three times the amount of actual damages sustained by the state;
 - (3) full reasonable attorney fees and costs in a case involving a fraudulent claim, agreement, contract, or understanding.

75. Under AS 09.58.100(4) the term “knowingly” means that a person, with or without specific intent to defraud, (A) has actual knowledge of the information; (B) acts in deliberate ignorance of the truth or falsity of the information; or (C) acts in reckless disregard of the truth or falsity of the information.

76. Under AS 47.05.290(10) “medical assistance provider” or “provider” means a person or organization that provides, attempts to provide, or claims to have provided services or products to a medical assistance recipient that may qualify for reimbursement under AS 47.07 or AS 47.08 or a person or organization that participates in or has applied to participate in a medical assistance program as a supplier of a service or product.

77. Under AS 09.58.100(8) (8) “obligation” means an established duty, whether or not fixed, arising from (A) an express or implied contractual grantor or grantee or licensor or licensee relationship; (B) a fee-based or similar relationship; (C) a statute or regulation; or (D) the retention of any overpayment.

78. For each unit of Acthar the Alaska Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar’s 1990 price as its Base Date AMP. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar’s 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Alaska Medicaid rebate obligation by millions of dollars.

79. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS’s requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, even though Mallinckrodt has corrected its Base Date AMP, it

knowingly and improperly continues to avoid its rebate obligation to the Alaska Medicaid Program.

80. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Alaska Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitates its improper avoidance and decreasing of that obligation.

81. The Alaska Medicaid program is jointly funded by the United States and Alaska. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the State Alaska have incurred significant financial losses.

82. By virtue of Mallinckrodt's conduct, the State of Alaska has suffered actual damages and is entitled to recover treble damages under the Alaska Medical Assistance False Claim and Reporting Act AS 09.58.010(c) to be determined at trial, plus civil penalties of not less than \$5,500 and not more than \$11,000 for each violation.

CLAIMS OF THE STATE OF CALIFORNIA

Count II – Reverse False Claims **(California False Claims Act, Cal. Gov't Code § 12651(7))**

83. The State of California re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

84. In addition to the facts alleged above, California asserts the following examples of Acthar claims for provider reimbursement that the California Medicaid Program paid, and for which Mallinckrodt wrongfully underpaid rebates:

- a. On or about May 14, 2013, a claim for five units of Acthar Gel (400 unit/5 ml vial) was submitted to the California Medicaid Program on behalf of Medicaid beneficiary C.C. On or about May 28, 2013, the Program reimbursed C.C.'s Medicaid provider \$28,578.51 for the claim.
- b. On or about March 31, 2015, a claim for 10 units of Acthar Gel (400 unit/5 ml vial) was submitted to the California Medicaid Program on behalf of Medicaid beneficiary E.V. On or about April 13, 2015, the Program reimbursed E.V.'s Medicaid provider \$64,269.17 for the claim.
- c. On or about November 7, 2016, a claim for 20 units of Acthar Gel (400 unit/5 ml vial) was submitted to the California Medicaid Program on behalf of Medicaid beneficiary A.F. On or about November 21, 2016, the Program reimbursed A.F.'s Medicaid provider \$135,598.71 for the claim.
- d. On or about October 23, 2019, a claim for five units of Acthar Gel (400 unit/5 ml vial) was submitted to the California Medicaid Program on behalf of Medicaid beneficiary J.C. On or about November 4, 2019, the Program reimbursed J.C.'s Medicaid provider \$38,905.20 for the claim.

For each of these sample claims, and for all the claims for Acthar submitted for reimbursement to the California Medicaid Program beginning the first quarter of 2013 through the first quarter of 2020, Mallinckrodt owed the California Medicaid Program rebates calculated in a

manner consistent with Mallinckrodt's obligations under the law and pursuant to the NDRA for Acthar as described herein.

85. For each unit of Acthar that a state Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter beginning the first quarter of 2013 through the first quarter of 2020, Mallinckrodt improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its total Medicaid rebate obligation to the State of California by tens of millions of dollars.

86. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016), and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, though Mallinckrodt has recently corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the California Medicaid Program for the period beginning the first quarter of 2013 through the first quarter of 2020.

87. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for the period beginning the first quarter of 2013 through the first quarter of 2020. Mallinckrodt knew that, if it did so, the California Medicaid Program's invoices it would receive each quarter would seek payment for much larger current rebate amounts and for reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date

AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system during the period beginning the first quarter of 2013 through the first quarter of 2020 further facilitated its improper avoidance and reduction of that obligation.

88. The California Medicaid Program is jointly funded by the United States and the State of California. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of California have incurred significant financial losses.

89. By virtue of Mallinckrodt's conduct, the State of California has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count III – Conversion
(California False Claims Act, Cal. Gov't Code § 12652(a)(4))

90. The State of California re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

91. Medicaid rebates collected by California offset the overall state and federal costs of California's Medicaid Program. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of public property or money used or to be used by the State of California. In particular, Mallinckrodt has retained for itself tens of millions of dollars that it should have paid in rebates to the California Medicaid Program.

92. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of California, and also knowingly delivered and caused to be

delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to the State of California.

93. Since no later than April 2016, Mallinckrodt has known that it delivered or caused to be delivered less than the full rebate amount due to the State of California for Acthar for rebate periods beginning the first quarter of 2013. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, though Mallinckrodt has recently taken corrective action with respect to its Base Date AMP and AMP reporting obligations, it continues to deliver, or causes to be delivered, less than all of the Medicaid rebates it owes for Acthar for the period beginning the first quarter of 2013 through the first quarter of 2020.

94. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for the period beginning the first quarter of 2013 through the first quarter of 2020. Mallinckrodt knew during that period that if it reported the correct 1990 Base Date AMP for Acthar as required, the California Medicaid Program invoices it would receive each quarter would seek payment for much larger current rebate amounts and for reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's wrongful refusal to update the DDR system caused the company to knowingly deliver less than the proper rebate amounts to Medicaid beginning the first quarter of

2013 through the first quarter of 2020, and has further caused Mallinckrodt to wrongfully retain those unpaid rebates to the present day.

95. The California Medicaid Program is jointly funded by the United States and the State of California. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of California have incurred significant financial losses.

96. By virtue of Mallinckrodt's conduct, the State of California has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count IV – Breach of Contract
(Third-Party Beneficiary)

97. The State of California re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

98. The Rebate Statute, 42 U.S.C. § 1396r-8, provides that for a drug manufacturer's drugs to be eligible for Medicaid reimbursement, the manufacturer must enter into a Rebate Agreement. 42 U.S.C. § 1396r-8(a)(1).

99. Since at least the first quarter of 2013, Mallinckrodt, either directly or through its predecessor in interest, has been party to an NDRA for Acthar with the United States. [See Exhibits 1-5.].

100. The State of California has at all relevant times been an intended third-party beneficiary of that agreement.

101. Under the terms of the NDRA, and in consideration for the privilege of having its drugs covered by Medicaid, Mallinckrodt, or its predecessor in interest, has at all relevant times been obligated to, among other things, accurately calculate and report all required pricing data on

Acthar, which includes Acthar's Base Date AMP, and to pay rebates to the State of California, which are in part calculated on the basis of this pricing data.

102. For the period beginning the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately calculate and report Acthar's Base Date AMP, and thereby failing to pay to the State of California the correct rebate amounts that Mallinckrodt owed to the state for Acthar during that period.

103. The California Medicaid Program is jointly funded by the United States and the State of California. As a result of Mallinckrodt's breach of the NDRA for Acthar, the State of California, as an intended third-party beneficiary to the NDRA, has incurred actual harm, which it is entitled to recover as legal damages; or, in the alternative, as restitution pursuant to the equitable common law doctrines of quasi-contract.

Count V – Unjust Enrichment/Restitution

104. The State of California re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

105. From the first quarter of 2013 through the first quarter of 2020, the California Medicaid program received substantially smaller Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely reported its Base Date AMP as alleged, Mallinckrodt would have been required to pay substantially larger rebates to California during that period. By retaining monies that were actually owed to California under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of California and to which it was not entitled.

106. By retaining the use and enjoyment of the monies that should have been paid to California pursuant to the Medicaid Rebate Program, Mallinckrodt has been unjustly enriched, and

is liable to account for and pay such amounts or the proceeds therefrom, which are to be determined according to proof, to the State of California.

CLAIMS OF THE STATE OF COLORADO

Count VI – False or Fraudulent Claim **(Colorado Medicaid False Claims Act, C.R.S. § 25.5-4-305(1)(b))**

107. The State of Colorado realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

108. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly made or caused to be made fraudulent statements material to a false or fraudulent claim to the United States and Colorado relating to its Base Date AMP for Acthar which caused Colorado to receive substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

109. The Colorado Medicaid Program is jointly funded by the United States and the State of Colorado. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Colorado Medicaid rebates for Acthar, the United States and the State of Colorado have incurred significant financial losses.

110. As a result of Mallinckrodt's conduct, Colorado suffered harm and is entitled to treble damages plus a civil penalty according to C.R.S. § 25.5-4-305 for each false claim.

Count VII – Refusal to Return Money **(Colorado Medicaid False Claims Act, C.R.S. § 25.5-4-305(1)(c))**

111. The State of Colorado realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

112. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Colorado Medicaid rebates for Acthar, Mallinckrodt has retained possession,

custody, or control of property or money used, or to be used, by Colorado. In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to Colorado. Medicaid rebates collected by Colorado offset the overall costs of Colorado Medicaid program.

113. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by Colorado, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to Colorado.

114. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, Mallinckrodt has taken no such corrective action and continues to deliver or cause to be delivered less than all of the Medicaid rebates it owes for Acthar.

115. From no later than April 2016 until the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, Colorado Medicaid program invoices it received each quarter would have sought payment for much larger rebate amounts and would also have sought reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper

rebate amounts, Mallinckrodt's refusal to update the DDR system further caused the company to deliver less than the proper rebate amounts to Colorado Medicaid.

116. By virtue of Mallinckrodt's conduct, Colorado has suffered actual damages and is entitled to recover treble damages plus a civil penalty according to C.R.S. § 25.5-4-305(1)(c) for each false claim.

Count VIII – Reverse False Claims
(Colorado Medicaid False Claims Act, C.R.S. § 25.5-4-305(1)(f))

117. The State of Colorado realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

118. For each unit of Acthar the Colorado Medicaid Program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Colorado Medicaid rebate obligation by tens of millions of dollars.

119. Since no later than 2013, through the first quarter of 2020, Mallinckrodt has knowingly and intentionally underpaid these lower rebates. Mallinckrodt calculated the amount of rebates it avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take.

120. Through the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Colorado Medicaid Program invoices it receives each quarter would have sought payment for much larger rebate amounts and would also have sought reimbursement of all prior underpayments

resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

121. The Colorado Medicaid Program is jointly funded by the United States and the State of Colorado. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Colorado Medicaid rebates for Acthar, the United States and the State of Colorado have incurred significant financial losses.

122. By virtue of Mallinckrodt's conduct, the State of Colorado has suffered actual damages and is therefore entitled to treble damages under the Colorado Medicaid False Claims Act, section : C.R.S. § 25.5-4-305(1)(f) to be determined at trial, plus a civil penalty according to C.R.S. § 25.5-4-305(1)(f) for each false claim.

Count IX – Breach of Contract

123. The State of Colorado realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

124. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Colorado was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

125. For the reasons discussed above, from the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

126. By virtue of this conduct, Colorado is entitled to damages and any other relief the Court deems appropriate.

Count X – Unjust Enrichment

127. The State of Colorado re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

128. The Colorado Medicaid program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely inflated its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to Colorado. By retaining monies that were actually owed to Colorado under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of Colorado and to which it was not entitled.

129. By retaining the use and enjoyment of the monies that should have been paid to Colorado pursuant to the Medicaid Rebate Program, Mallinckrodt has been unjustly enriched, and is liable to account for and pay such amounts or the proceeds therefrom, which are to be determined at trial, to the State of Colorado.

Count XI– Civil Theft
(C.R.S. § 18-4-405)

130. The State of Colorado realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

131. For each unit of Acthar the Colorado Medicaid Program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner,

Mallinckrodt has avoided and decreased its Colorado Medicaid rebate obligation by tens of millions of dollars.

132. Since no later than 2013, through the first quarter of 2020, Mallinckrodt has knowingly and intentionally underpaid these lower rebates. Mallinckrodt calculated the amount of rebates it avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take.

133. Through the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Colorado Medicaid Program invoices it received each quarter would have sought payment for much larger rebate amounts and would also have sought reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

134. The Colorado Medicaid Program is jointly funded by the United States and the State of Colorado. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Colorado Medicaid rebates for Acthar, the United States and the State of Colorado have incurred significant financial losses.

135. By virtue of Mallinckrodt's conduct, Mallinckrodt knowingly obtained and exercised control over Colorado Medicaid rebates for Acthar without authorization and with the intent to permanently deprive the Colorado Medicaid Program of the use or benefit of Colorado Medicaid rebates for Acthar. The State of Colorado has suffered actual damages and is therefore entitled to treble damages and other relief to be determined at trial.

CLAIMS OF THE STATE OF CONNECTICUT

Count XII– Reverse False Claims **(Connecticut state False Claims Act, Conn. Gen. Stat. §§4-275, 4-277)**

136. The State of Connecticut repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

137. The Connecticut state False Claims Act provides, in pertinent part, that no person shall:

- (1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;
- (2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program;
- (3) Conspire to commit a violation of this section;
- (4) Having 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;
- (5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a state-administered health or human services program and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true; ... or
- (8) Knowingly 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.

Conn. Gen. Stat. §4-275(a).

138. Any person who violates Conn. Gen. Stat. §4-275(a) is liable to the State of Connecticut for:

- (1) A civil penalty of not less than five thousand five hundred dollars or more than eleven thousand dollars, or as adjusted from time to time by the federal Civil Penalties Inflation Adjustment Act of 1990, 28 USC 2461, (2) three times the amount of damages that the state sustains because of the act of that person, and (3) the costs of investigation and prosecution of such violation. Liability under this section shall be joint and several for any violation of this section committed by two or more persons.

Conn. Gen. Stat. §4-275(b).

139. The provisions of Conn. Gen. Stat. §4-274(1) define the terms “knowing” and “knowingly” to mean: “that a person, with respect to information: (A) Has actual knowledge of the information; (B) acts in deliberate ignorance of the truth or falsity of the information; or (C) acts in reckless disregard of the truth or falsity of the information, without regard to whether the person intends to defraud.”

140. For each unit of Acthar the Connecticut Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar’s 1990 price as its Base Date AMP. For every quarter since 2013, through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar’s 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Connecticut Medicaid rebate obligation by millions of dollars.

141. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS’s requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. From the first quarter of 2013 through the first quarter of 2020 Mallinckrodt has taken no such corrective action and knowingly and improperly continued to avoid and decrease its rebate obligation to Connecticut Medicaid.

142. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knows that if it did so, the

Connecticut Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

143. The Connecticut Medicaid program is jointly funded by the United States and the State of Connecticut. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of Connecticut have incurred significant financial losses.

144. By virtue of Mallinckrodt's conduct, the State of Connecticut has suffered actual damages and is entitled to recover the following relief for each instance of unlawful conduct, pursuant to Conn. Gen. Stat. §4-275(a):

1. A civil penalty of not less than five thousand five hundred dollars or more than eleven thousand dollars, or as adjusted from time to time by the federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. §2461, for each violation of Conn. Gen. Stat. §4-275(a);
2. Three times the amount of damages that the State of Connecticut sustained because of the acts of the Defendant; and
3. Costs of investigation and prosecution of this action.

Count XIII – Conversion
(Connecticut state False Claims Act, Conn. Gen. Stat. §§4-275, 4-277)

145. The State of Connecticut repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

146. The Connecticut state False Claims Act provides, in pertinent part, that no person shall:

- (1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;
- (2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program;
- (3) Conspire to commit a violation of this section;
- (4) Having 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;
- (5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a state-administered health or human services program and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true; ... or
- (8) Knowingly 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.

Conn. Gen. Stat. §4-275(a).

147. Any person who violates Conn. Gen. Stat. §4-275(a) is liable to the State of Connecticut for:

- (1) A civil penalty of not less than five thousand five hundred dollars or more than eleven thousand dollars, or as adjusted from time to time by the federal Civil Penalties Inflation Adjustment Act of 1990, 28 USC 2461, (2) three times the amount of damages that the state sustains because of the act of that person, and (3) the costs of investigation and prosecution of such violation. Liability under this section shall be joint and several for any violation of this section committed by two or more persons.

Conn. Gen. Stat. §4-275(b).

148. The provisions of Conn. Gen. Stat. §4-274(1) define the terms “knowing” and “knowingly” to mean: “that a person, with respect to information: (A) Has actual knowledge of the information; (B) acts in deliberate ignorance of the truth or falsity of the information; or (C)

acts in reckless disregard of the truth or falsity of the information, without regard to whether the person intends to defraud.”

149. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Connecticut Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the State of Connecticut. In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to the State of Connecticut. Medicaid rebates collected by the State of Connecticut offset the overall costs of the State of Connecticut Medicaid program.

150. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of Connecticut, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 through the first quarter of 2020 for Acthar, to the State of Connecticut.

151. Since no later than April 2016, Mallinckrodt has known that it delivered or caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 through the first quarter of 2020. Mallinckrodt understood that CMS’s requested corrective action meant using Acthar’s 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. Mallinckrodt had taken no such corrective action from 2013 through the first quarter of 2020 and during that period continued to deliver or cause to be delivered less than all of the Medicaid rebates it owed for Acthar.

152. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knows that, if it did so, the Connecticut Medicaid program invoices it receives each quarter would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

153. The Connecticut Medicaid program is jointly funded by the United States and the State of Connecticut. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of Connecticut have incurred significant financial losses.

154. By virtue of Mallinckrodt's conduct, the State of Connecticut has suffered actual damages and is entitled to recover the following relief for each instance of unlawful conduct, pursuant to Conn. Gen. Stat. §4-275(a):

1. A civil penalty of not less than five thousand five hundred dollars or more than eleven thousand dollars, or as adjusted from time to time by the federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. §2461, for each violation of Conn. Gen. Stat. §4-275(a);
2. Three times the amount of damages that the State of Connecticut sustained because of the acts of the Defendant; and
3. Costs of investigation and prosecution of this action.

Count XIV – Unjust Enrichment

155. The State of Connecticut re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

156. The State of Connecticut Medicaid program received substantially smaller Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely inflated its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to the State of Connecticut. By retaining monies that were actually owed to the State of Connecticut under the Medicaid Rebate Program, Mallinckrodt retained money that is the property of the State of Connecticut to which it was not entitled.

157. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that should have been paid to the State of Connecticut, pursuant to the Medicaid Rebate Program, absent Mallinckrodt's false reporting of its Base Date AMP for Acthar.

158. As a result of Mallinckrodt's conduct, the State of Connecticut suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count XV – Common Law Fraud

159. The State of Connecticut repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

160. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and the State of Connecticut of its Base Date AMP for Acthar.

161. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

162. Mallinckrodt intended that the State of Connecticut rely upon these material misrepresentations.

163. The State of Connecticut did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, from 2013 through the first quarter of 2020, the State of Connecticut received substantially lower rebate payments for Acthar than it would have otherwise been entitled to receive if Mallinckrodt had accurately reported its Base Date AMP for Acthar.

164. As a result of Mallinckrodt's conduct, the State of Connecticut suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count XVI – Breach of Contract

165. The State of Connecticut repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

166. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Connecticut was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

167. For the reasons discussed above, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

168. By virtue of this conduct, the State of Connecticut is thus entitled to damages and any other relief the Court deems appropriate.

Count XVII – Disgorgement

169. The State of Connecticut repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

170. Mallinckrodt failed to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement and retained money that should have been paid to the States, including the State of Connecticut.

171. This Court has the equitable power to order defendant Mallinckrodt to disgorge the entire amount of improperly-retained rebate payments that should have been paid to the States.

172. The State of Connecticut seeks disgorgement of all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement.

CLAIMS OF THE STATE OF DELAWARE

Count XVIII – Reverse False Claims **(Delaware False Claims and Reporting Act, 6 Del. C. § 1201(a)(7))**

173. The State of Delaware re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

174. For each unit of Acthar the Delaware Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Delaware Medicaid rebate obligation by tens of millions of dollars.

175. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it

would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, Mallinckrodt has taken no such corrective action and knowingly and improperly continues to avoid and decrease its rebate obligation to Delaware Medicaid.

176. Mallinckrodt also refuses to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that if it did so, the Delaware Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitates its improper avoidance and decreasing of that obligation.

177. The Delaware Medicaid program is jointly funded by the United States and the State of Delaware. Because of Mallinckrodt's knowing and improper failure to pay the correct amount of Delaware Medicaid rebates for Acthar, the United States and the State of Delaware have incurred significant financial losses.

178. By Mallinckrodt's conduct, the State of Delaware has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XIX – Conversion
(Delaware False Claims and Reporting Act, 6 Del. C. § 1201(a)(4))

179. The State of Delaware re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

180. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Delaware Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. Mallinckrodt has

retained for itself tens of millions of dollars that it should have paid in rebates to the Delaware Medicaid Program. Medicaid rebates collected by Delaware offset the overall cost of the Delaware Medicaid program.

181. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of Delaware, and Mallinckrodt knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to the State of Delaware.

182. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, Mallinckrodt has taken no such corrective action and continues to deliver or cause to be delivered less than all of the Medicaid rebates it owes for Acthar.

183. Mallinckrodt also refuses to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that if it did so, the Delaware Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitates its improper avoidance and decreasing of that obligation.

184. The Delaware Medicaid program is jointly funded by the United States and the State of Delaware. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of Delaware have incurred significant financial losses.

185. By Mallinckrodt's conduct, the State of Delaware has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

CLAIMS OF THE DISTRICT OF COLUMBIA

Count XX – False or Fraudulent Statements **(False Claims Act, D.C. Code § 2-381.03(a)(2))**

186. The District repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

187. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly made or caused to be made fraudulent statements material to a false or fraudulent claim to the United States and the District relating to its Base Date AMP for Acthar which caused the District to receive substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

188. As a result of Mallinckrodt's conduct, the District suffered harm and is entitled to treble damages plus a civil penalty according to D.C. Code § 2-381.03 for each false claim.

Count XXI – Conversion **(False Claims Act, D.C. Code § 2-381.03(a)(3))**

189. The District re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

190. From the first quarter of 2013 and continuing through the present, by failing to reimburse the District Medicaid Program rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the District. In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to the District. Medicaid rebates collected by the District offset the overall costs of the District Medicaid program.

191. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the District, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to the District.

192. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the District Medicaid Program.

193. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that, if it did so, the District Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from

Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's refusal to update the DDR system further causes the company to deliver less than the proper rebate amounts to the District Medicaid.

194. By virtue of Mallinckrodt's conduct, the District has suffered actual damages and is entitled to recover treble damages plus a civil penalty according to D.C. Code § 2-381.03 for each false claim.

Count XXII – Reverse False Claims
(False Claims Act, D.C. Code § 2-381.03(a)(6))

195. The District re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

196. For each unit of Acthar the District Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. From the first quarter of 2013, through the first quarter of 2020, Mallinckrodt has knowingly and improperly avoided or decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided or decreased its District Medicaid rebate obligation by millions of dollars.

197. Since no later than April 2016, Mallinckrodt paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take.

To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the District Medicaid Program.

198. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the District Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitates its improper avoidance or decreasing of that obligation.

199. The District Medicaid program is jointly funded by the United States and the District. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the District has incurred significant financial losses.

200. By virtue of Mallinckrodt's conduct, the District has suffered actual damages and is entitled to recover treble damages plus a civil penalty according to D.C. Code § 2-381.03 for each false claim.

Count XXIII – Unjust Enrichment

201. The District of Columbia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

202. If Mallinckrodt had not used the incorrect Base Date AMP for Acthar from January 1, 2013 through the first quarter of 2020, Mallinckrodt would have been required to pay substantially larger rebates to the District. By retaining monies that were actually owed to the

District under the MDRP, Mallinckrodt retained money that was the property of the District Medicaid programs and to which it was not entitled.

203. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to the District pursuant to the MDRP had it used the correct Base Date AMP to calculate the amount of Medicaid rebates it owed for Acthar.

CLAIMS OF THE STATE OF FLORIDA

Count XXIV – Reverse False Claims **(Florida False Claims Act, Fla. Stat. §68.082(2)(g))**

204. The State of Florida re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

205. For each unit of Acthar the Florida Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Florida Medicaid rebate obligation by tens of millions of dollars.

206. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. Until recently, Mallinckrodt had taken no such corrective action. As such, Mallinckrodt knowingly and improperly avoided and decreased its rebate obligation to Florida

Medicaid and continues to withhold monies owed to the Florida Medicaid program due to its underpayments of Acthar rebates.

207. Since no later than January 2013, and continuing through the first quarter of 2020, Mallinckrodt refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Florida Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

208. The Florida Medicaid program is jointly funded by the United States and the State of Florida. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Florida Medicaid rebates for Acthar, the United States and the State of Florida have incurred significant financial losses.

209. By virtue of Mallinckrodt's conduct, the State of Florida has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XXV – Conversion
(Florida False Claims Act, Fla. Stat. §68.082(2)(d))

210. The State of Florida re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

211. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Florida Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. In particular, Mallinckrodt

has retained for itself tens of millions of dollars that it should have paid in rebates to the Florida Medicaid Program. Medicaid rebates collected by Florida offset the overall cost of the Florida Medicaid program.

212. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of Florida, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to the State of Florida.

213. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. Until recently, Mallinckrodt had taken no such corrective action. As such, Mallinckrodt delivered or caused to be delivered less than all of the Medicaid rebates it owes for Acthar.

214. Since no later than January 2013, and continuing through the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Florida Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its delivery of

less than all of the Medicaid rebates it owes for Acthar.

215. The Florida Medicaid program is jointly funded by the United States and the State of Florida. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of Florida have incurred significant financial losses.

216. By virtue of Mallinckrodt's conduct, the State of Florida has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

CLAIMS OF THE STATE OF GEORGIA

Count XXVI – Reverse False Claims **(Georgia False Medicaid Claims Act, O.C.G.A. §49-4-168.1(a)(7))**

217. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

218. For each unit of Acthar the Georgia Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its obligation to pay rebates to the Georgia Medicaid Program by tens of millions of dollars.

219. Since no later than 2013, Mallinckrodt has known that it avoided and decreased its obligation to pay higher rebates to the Georgia Medicaid Program. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also

contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, Mallinckrodt has taken no such corrective action and knowingly and improperly continues to avoid and decrease its rebate obligation to Georgia Medicaid.

220. Since no later than 2013, and continuing through the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Georgia Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system materially facilitated its improper avoidance and decreasing of that obligation.

221. The Georgia Medicaid program is jointly funded by the United States and the State of Georgia. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Georgia Medicaid rebates for Acthar, the United States and the State of Georgia have incurred significant financial losses.

222. By virtue of Mallinckrodt's conduct, the State of Georgia has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XXVII – Conversion
(Georgia False Medicaid Claims Act, O.C.G.A. §49-4-168.1(a)(4))

223. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

224. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Georgia Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the Georgia Medicaid Program. In particular, Mallinckrodt has retained for itself tens of millions of dollars that it should have paid in rebates to the Georgia Medicaid Program. Medicaid rebates collected by Georgia offset the overall cost of the Georgia Medicaid program.

225. Since no later than 2013, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of Georgia, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to the State of Georgia.

226. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, Mallinckrodt has taken no such corrective action and continues to deliver or cause to be delivered less than all of the Medicaid rebates it owes for Acthar.

227. Since no later than 2013, and continuing through the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Georgia Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek

reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

228. The Georgia Medicaid program is jointly funded by the United States and the State of Georgia. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of Georgia have incurred significant financial losses.

229. By virtue of Mallinckrodt's conduct, the State of Georgia has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XXVIII – Unjust Enrichment

230. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

231. This is a claim for the recovery of monies by which Mallinckrodt has been unjustly enriched.

232. The Georgia Medicaid Program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely reported its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to Georgia. By falsely reporting its Base Date AMP, Mallinckrodt was able to retain profits for Acthar and avoid paying monies owed to Georgia.

233. By retaining monies that were actually owed to Georgia under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of Georgia and to which it was not entitled.

234. Mallinckrodt has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Georgia, plus costs, expenses, and the maximum amount of interest available under law.

Count XXIV – Fraud and Deceit

235. The State of Georgia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

236. Per Georgia statute, “[f]raud, accompanied by damage to the party defrauded, always gives a right of action to the injured party.” O.C.G.A. § 51-6-1.

237. From the first quarter of 2013 and continuing through the present, Mallinckrodt knowingly made and/or caused to be made fraudulent statements to the United States and the State of Georgia that the Base Date for Acthar was 2013. These statements were fraudulent because the correct Base Date AMP for Acthar is 1990.

238. Mallinckrodt made the fraudulent statements with the intent and purpose of deceiving the State of Georgia regarding the amount it owed in rebates to the Georgia Medicaid Program.

239. Georgia reasonably relied upon Mallinckrodt’s fraudulent misrepresentations. As a proximate result, between 2013 through the present, Georgia received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

240. As a result of Mallinckrodt's conduct, the State of Georgia suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

CLAIMS OF THE STATE OF ILLINOIS

Count XXX – Unjust Enrichment

241. The State of Illinois re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

242. If Mallinckrodt had not used the incorrect Base Date AMP for Acthar from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt would have been required to pay substantially larger rebates to Illinois. By retaining monies that were actually owed to Illinois under the MDRP, Mallinckrodt retained money that was the property of the Illinois Medicaid program and to which it was not entitled.

243. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to Illinois pursuant to the MDRP had it used the correct Base Date AMP to calculate the amount of Medicaid rebates it owed for Acthar.

Count XXXI – Reverse False Claims **(Illinois False Claims Act, 740 ILCS 175/3(a)(1)(G))**

244. The State of Illinois re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

245. For each unit of Acthar the Illinois Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter including the first quarter of 2013 through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this

manner, Mallinckrodt has avoided and decreased its Illinois Medicaid rebate obligation by millions of dollars.

246. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates despite requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and paying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had avoided from 2013 through April 2016, and the percentage of rebates it would avoid going forward if it refused to take the corrective action CMS requested and knowingly chose to defy CMS. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly avoids and decreases its rebate obligation to the Illinois Medicaid program.

247. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for seven years. Mallinckrodt knew that if it did so, the Illinois Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

248. The Illinois Medicaid program is jointly funded by the United States and State of Illinois. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, Illinois has incurred significant financial losses.

249. By virtue of Mallinckrodt's conduct, Illinois has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XXXII – Conversion
(Illinois False Claims Act, 740 ILCS 175/3(a)(1)(D))

250. The State of Illinois re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

251. By failing to reimburse the Illinois Medicaid Program for rebate amounts for Acthar that it underpaid, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to the State of Illinois. Medicaid rebates collected by the State of Illinois offset the overall costs of the Illinois Medicaid program.

252. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by Illinois. Mallinckrodt has also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from the first quarter of 2013 through the first quarter of 2020 for Acthar, to Illinois.

253. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from the first quarter of 2013 through the first quarter of 2020. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. Though

Mallinckrodt has recently corrected its Base Date AMP, it has still delivered or caused to be delivered less than all of the Medicaid rebates it owes for Acthar.

254. Mallinckrodt refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for seven years. Mallinckrodt knew that if it did so, the Illinois Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's seven-year-long refusal to update the DDR system further caused the company to deliver less than the proper rebate amounts to Illinois Medicaid.

255. By virtue of Mallinckrodt's conduct, Illinois has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XXXIII – Common Law Fraud

256. The State of Illinois repeats and re-alleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

257. From the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and the State of Illinois regarding its Base Date AMP for Acthar.

258. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, and failed to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

259. Mallinckrodt intended that Illinois act or refrain from acting in justifiable reliance on these misrepresentations.

260. Illinois did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, in the calendar quarters from January 2013 through March 2020, the State of Illinois received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

261. As a result of Mallinckrodt's conduct, the State of Illinois suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count XXXIV – Breach of Contract

262. The State of Illinois repeats and re-alleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

263. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Illinois was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

264. For the reasons discussed above, from the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

265. By virtue of this conduct, Illinois is thus entitled to damages and any other relief the Court deems appropriate.

Count XXXV – Disgorgement

266. The State of Illinois repeats and re-alleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

267. Mallinckrodt failed to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement and retained money that should have been paid to the States, including the State of Illinois.

268. This Court has the equitable power to order defendant Mallinckrodt to disgorge the entire amount of improperly-retained rebate payments that should have been paid to the States.

269. The State of Illinois seeks disgorgement of all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement.

CLAIMS OF THE STATE OF INDIANA

Count XXXVI – Reverse False Claims **(Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5–11–5.5–1, *et seq.*)**

270. The State of Indiana re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

271. The Indiana False Claims and Whistleblower Protection Act (“INFCA”), Ind. Code § 5–11–5.5–2(b), provides in pertinent part, that a person who knowingly or intentionally:

(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;

is ... liable to the state for a civil penalty of at least five thousand dollars (\$5,000) and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

272. The INFCA defines the terms “knowing”, “knowingly”, or “known” to mean that a person, regarding information relating to a claim, “(A) has actual knowledge of the information; (B) acts in deliberate ignorance of the truth or falsity of the information; or (C) acts in reckless disregard of the truth or falsity of the information.” Ind. Code § 5–11–5.5–1(4).

273. For each unit of Acthar the Indiana Medicaid program purchased, Mallinckrodt was

aware of its obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. Mallinckrodt also knew that its Base Date AMP submissions in the Medicaid DDR system would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Mallinckrodt was obligated to pay to the States, including Indiana, for Acthar.

274. For every quarter, commencing with the quarter beginning on January 1, 2013 and continuing through the quarter ending on June 30, 2013, Mallinckrodt made false quarterly submissions to CMS using its 2013 price as its Base Date AMP with respect to Acthar.

275. For every quarter, commencing with the quarter beginning on January 1, 2013 and continuing through the quarter ending on June 30, 2013, Mallinckrodt used a 2013 Base Date AMP instead of a 1990 Base Date AMP, and thereby created and used false records or statements to improperly avoid an obligation to pay or transmit to the state millions of dollars in Indiana Medicaid rebate obligations.

276. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, Mallinckrodt has taken no such corrective action and knowingly and improperly continues to avoid and decrease its rebate obligation to Indiana Medicaid.

277. Mallinckrodt also refuses to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that if it did so, the Indiana Medicaid program

invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitates its improper avoidance and decreasing of that obligation.

278. The Indiana Medicaid program is jointly funded by the United States and the State of Indiana. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Indiana Medicaid rebates for Acthar, the United States and the State of Indiana have incurred significant financial losses.

279. By virtue of Mallinckrodt's illegal conduct, the State of Indiana has suffered actual damages and is entitled to recover from Mallinckrodt treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XXXVII – Reverse False Claims
(Indiana Medicaid False Claims and Whistleblower Protection Act,
Ind. Code § 5–11–5.7–1, et seq.)

280. The State of Indiana re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

281. The Indiana Medicaid False Claims and Whistleblower Protection Act (“INMFCA”), Ind. Code § 5–11–5.7–2(a), provides in pertinent part, that a person who:

(3) 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 ... (6) 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;

is ... liable to the state for a civil penalty of at least five thousand five hundred dollars (\$5,500) and not more than eleven thousand dollars (\$11,000), as adjusted by the federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, Public Law 101-410), and for up to three (3) times the amount of damages

sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

282. The INMFCA defines the terms “knowing”, “knowingly”, or “known” to mean that a person, regarding information relating to a claim, “(A) has actual knowledge of the information; (B) acts in deliberate ignorance of the truth or falsity of the information; or (C) acts in reckless disregard of the truth or falsity of the information; and requires no proof of specific intent to defraud.” Ind. Code § 5–11–5.7–1(b)(4).

283. The INMFCA defines the term “material” to mean having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. Ind. Code § 5–11–5.7–1(b)(5).

284. The INMFCA defines the term “obligation” to mean “an established duty, whether or not the duty is fixed, arising from: (A) an express or implied contractual relationship; (B) a grantor-grantee relationship; (C) a licensor-licensee relationship; (D) a fee-based or similar relationship; (E) a statute; (F) a rule or regulation; or (G) the retention of an overpayment. Ind. Code § 5–11–5.7–1(b)(6).

285. For each unit of Acthar the Indiana Medicaid program purchased, Mallinckrodt was aware of its obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar’s 1990 price as its Base Date AMP. For every quarter since the quarter beginning on July 1, 2014, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar’s 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Indiana Medicaid rebate obligation by millions of dollars.

286. For every quarter, commencing with the quarter beginning on July 1, 2013 through the first quarter of 2020, Mallinckrodt provided false quarterly submissions to CMS using its 2013 price as its Base Date AMP with respect to Acthar.

287. For every quarter, commencing with the quarter beginning on July 1, 2013 and continuing through the present, by failing to reimburse the Indiana Medicaid Program for rebate amounts for Acthar that it has underpaid, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government and knowingly delivered, or caused to be delivered, less than all of that money or property.

288. For every quarter, commencing with the quarter beginning on July 1, 2013 through the first quarter of 2020, Mallinckrodt knowingly made, used, or caused to be made or used, false records or statements regarding its Base Date AMP for Acthar that were material to its obligation to pay or transmit money or property to the Indiana Medicaid Program.

289. For every quarter, commencing with the quarter beginning on July 1, 2013 through the first quarter of 2020, Mallinckrodt knowingly concealed or knowingly and improperly decreased its obligation to pay or transmit money or property to the Indiana Medicaid Program. By using Acthar's 2013 price as its Base Date AMP, Mallinckrodt improperly decreased its rebate obligation by paying a much lower rebate amount.

290. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then

directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the Indiana Medicaid Program.

291. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Indiana Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

292. The Indiana Medicaid program is jointly funded by the United States and the State of Indiana. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Indiana Medicaid rebates for Acthar, the United States and the State of Indiana have incurred significant financial losses.

293. By virtue of Mallinckrodt's illegal conduct, the State of Indiana has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XXVIII – Conversion
(Indiana Crime Victims Relief Act, Ind. Code §34-24-3-1)

294. The State of Indiana re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

295. The Indiana Crime Victims Relief Act ("INCVRA"), Ind. Code § 34-24-3-1(a), provides in pertinent part, that "[i]f a person ... suffers a pecuniary loss as a result of a violation of Ind. Code 35-43... the person may bring a civil action against the person who caused the loss

for the following:

(1) An amount not to exceed three (3) times: (A) the actual damages of the person suffering the loss ... ; (2) the costs of the action; (3) a reasonable attorney's fee; (4) actual travel expenses that are not otherwise reimbursed under subdivisions (1) through (3) and are incurred by the person suffering loss to: (A) have the person suffering loss or an employee or agent of that person file papers and attend court proceedings related to the recovery of a judgment under this chapter; or (B) provide witnesses to testify in court proceedings related to the recovery of a judgment under this chapter; (5) a reasonable amount to compensate the person suffering loss for time used to: (A) file papers and attend court proceedings related to the recovery of a judgment under this chapter; or (B) travel to and from activities described in clause (A); (6) actual direct and indirect expenses incurred by the person suffering loss to compensate employees and agents for time used to: (A) file papers and attend court proceedings related to the recovery of a judgment under this chapter; or (B) travel to and from activities described in clause (A); and (7) all other reasonable costs of collection.

296. "A person who knowingly or intentionally exerts unauthorized control over property of another person commits criminal conversion, a Class A misdemeanor." Ind. Code § 35-43-4-3.

297. "Under Indiana law, a person who has suffered a pecuniary loss as a result of a criminal conversion may bring a civil action to recover the loss. A claimant in a civil action must only show that the defendant committed the criminal act by a preponderance of the evidence." *Smeigh v. Johns Manville, Inc.*, 643 F.3d 554, 563 (7th Cir. 2011) (internal citations omitted). The State of Indiana, through its Attorney General, has authority to proceed as a plaintiff under the INCVRA. *Mizen v. State ex rel. Zoeller*, 72 N.E.3d 458, 470-71 (Ind. Ct. App. 2017).

298. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Indiana Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. In particular, Mallinckrodt has retained for itself tens of millions of dollars that it should have paid in rebates to the Indiana Medicaid Program. Medicaid rebates collected by Indiana offset the overall cost of the Indiana Medicaid program.

299. For each unit of Acthar the Indiana Medicaid program purchased, Mallinckrodt was aware of its obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP.

300. For every quarter since the quarter beginning on January 1, 2013 through the first quarter of 2020, Mallinckrodt has knowingly or intentionally exerted unauthorized control over property of the State of Indiana by having avoided and decreased this obligation and paying a much lower rebate amount using Acthar's 2013 price as its Base Date AMP instead.

301. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, Mallinckrodt has taken no such corrective action and continues to knowingly or intentionally exert unauthorized control over property of the State of Indiana.

302. Mallinckrodt also refuses to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that if it did so, the Indiana Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitates its knowing or intentional exertion of unauthorized control over property of the

State of Indiana.

303. The Indiana Medicaid program is jointly funded by the United States and the State of Indiana. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Indiana Medicaid rebates for Acthar, the United States and the State of Indiana have incurred significant financial losses.

304. By virtue of Mallinckrodt's illegal conduct, the State of Indiana has suffered a pecuniary loss and is entitled to recover from Mallinckrodt treble damages, costs, reasonable attorney's fees, and other expenses pursuant to the INCVRA.

CLAIMS OF THE STATE OF LOUISIANA

Count XXXIV – Reverse False Claims **(Louisiana Medical Assistance Programs Integrity Law, LSA-R.S. 46:438.3(C))**

305. The State of Louisiana re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

306. For each unit of Acthar the State of Louisiana Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Medicaid rebate obligation by millions of dollars.

307. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it

would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, Mallinckrodt has taken no such corrective action and knowingly and improperly continues to avoid and decrease its rebate obligation to Louisiana Medicaid.

308. Mallinckrodt also refuses to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that if it did so, the Louisiana Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitates its improper avoidance and decreasing of that obligation.

309. The State of Louisiana's Medicaid program is jointly funded by the United States and Louisiana. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, Louisiana has incurred significant financial losses.

310. By virtue of Mallinckrodt's conduct, Louisiana has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XL – Attempt to Defraud
(Louisiana Medical Assistance Programs Integrity Law, LSA-R.S. 46:438.3(D))

311. The State of Louisiana re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

312. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Louisiana Medicaid rebates for Acthar, Mallinckrodt has attempted to defraud the Louisiana Medical Assistance Program through misrepresentation by failing to fully or truthfully disclose the 1990 Base Date AMP for Acthar and by reporting an incorrect Base Date Amp.

313. Since no later than April 2016, Mallinckrodt has attempted to defraud Louisiana through misrepresentation by knowingly misrepresenting its Base Date AMP for Acthar in a scheme to underpay Medicaid rebate amounts from 2013 forward for Acthar to Louisiana.

314. Since no later than April 2016, Mallinckrodt knew that it was misrepresenting the Base Date Amp due for Acthar for the rebate periods from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, Mallinckrodt has taken no such corrective action and continues to misrepresent its actual Base Date Amp in an effort to deliver less than all of the Medicaid rebates it owes for Acthar.

315. Mallinckrodt also refuses to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that, if it did so, the Louisiana Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's refusal to update the DDR system further causes the company to deliver less than the proper rebate amounts to Louisiana Medicaid.

316. By virtue of Mallinckrodt's conduct, Louisiana has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XLI – Fraud

317. The State of Louisiana repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

318. From the first quarter of 2013 and continuing through the present, Mallinckrodt made and/or caused to be made misrepresentations to the United States and the State of Louisiana of its Base Date AMP for Acthar.

319. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with an intent to deceive the United States and the State of Louisiana.

320. Mallinckrodt intended that the United States and Louisiana act or refrain from acting in justifiable reliance on these misrepresentations.

321. Louisiana did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, between 2013 through present, Louisiana received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

322. As a result of Mallinckrodt's conduct, the State of Louisiana suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count XLII – Breach of Contract

323. The State of Louisiana repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

324. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Louisiana was an intended third party beneficiary of that contract. Under the

terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

325. For the reasons discussed above, from the first quarter of 2013 and continuing through the present, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

326. By virtue of this conduct, Louisiana is thus entitled to damages and any other relief the Court deems appropriate.

Count XLIII – Enrichment Without Cause
(La.C.C. 2298)

327. The State of Louisiana re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

328. Louisiana Civil Code Article 2298 provides that a person who has been enriched without cause at the expense of another is bound to compensate that person.

329. If Mallinckrodt had not used the incorrect Base Date AMP for Acthar since January 1, 2013, Mallinckrodt would have been required to pay substantially larger rebates to Louisiana. By retaining monies that were actually owed to Louisiana under the MDRP, Mallinckrodt retained money that was the property of the Louisiana Medicaid programs and to which it was not entitled.

330. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to Louisiana pursuant to the MDRP had it used the correct Base Date AMP to calculate the amount of Medicaid rebates it owed for Acthar.

CLAIMS OF THE STATE OF MARYLAND

Count XLIV – Violation of the Maryland False Health Claims Act (Reverse False Claim) **(MD Code, Health - General, § 2-601, *et seq.*)**

331. Maryland re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

332. Maryland’s False Health Claims Act (“MFHCA”) provides, in relevant part, that a person may not:

§ 2-602(a)(7): 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 other property to the State;

§ 2-602(a)(8): Knowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State[.]

Violations of the MFHCA result in liability to the State for both (i) a civil penalty of not more than \$10,000 for each violation; and (ii) an additional amount of not more than three times the amount of the State’s resulting damages. MD Code, Health - General, § 2-602(b)(1).

333. For purposes of the MFHCA, the terms “knowing” and “knowingly” 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. No proof of specific intent to defraud is required. MD Code, Health - General, § 2-601(f)(1).

334. The MFHCA defines the term “obligation” to mean:

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. MD Code, Health - General, § 2-601(h).

335. For purposes of the MFHCA, the term “material” means “having a natural tendency to influence or be capable of influencing the payment or receipt of money or other property.” MD Code, Health - General, § 2-601(g).

336. For each unit of Acthar the Maryland Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar’s 1990 price as its Base Date AMP. From the first quarter of 2013 until the end of the first quarter of 2020, Mallinckrodt improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar’s 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt avoided and decreased its Maryland Medicaid rebate obligation by millions of dollars.

337. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS’s requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested, and then directed, it to take. Mallinckrodt continued in its refusal through the end of the first quarter of 2020.

338. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Maryland Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt’s use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt’s

refusal to update the DDR system further facilitated its improper avoidance and reduction of that obligation.

339. The Maryland Medicaid program is jointly funded by the United States and Maryland. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, Maryland has incurred significant financial losses.

340. By virtue of Mallinckrodt's conduct, Maryland has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XLV – Violation of the Maryland False Health Claims Act (Conversion)
(MD Code, Health - General, § 2-602(a)(4))

341. Maryland re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

342. The MFHCA provides in relevant part that a person may not:

§ 2-602(a)(4): Have 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;

343. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Maryland Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to Maryland. Medicaid rebates collected by Maryland offset the overall costs of the Maryland Medicaid program.

344. Since no later than April 2016, Mallinckrodt has knowingly possessed money used by, or to be used by, Maryland and also knowingly delivered and caused to be delivered less than

all of this money to Maryland, in the form of unpaid Medicaid rebate amounts for Acthar from 2013 through the first quarter of 2020.

345. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 until the end of the first quarter of 2020. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, by refusing to take the corrective action CMS warned it to take. Mallinckrodt then continued in its refusal until the end of the first quarter of 2020.

346. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that, if it did so, the Maryland Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's refusal to update the DDR system caused the company to deliver less than the proper rebate amounts to Maryland Medicaid.

347. By virtue of Mallinckrodt's conduct, Maryland has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count XLVI – Common Law Fraud

348. Maryland repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

349. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and Maryland of its Base Date AMP for Acthar.

350. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

351. Mallinckrodt intended that Maryland act or refrain from acting in justifiable reliance on these misrepresentations.

352. Maryland did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, between 2013 through the first quarter of 2020, Maryland received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

353. As a result of Mallinckrodt's conduct, Maryland suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count XLVII – Breach of Contract

354. Maryland repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

355. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. Maryland was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

366. For the reasons discussed above, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

367. By virtue of this conduct, Maryland is thus entitled to damages and any other relief the Court deems appropriate.

Count XLVIII – Unjust Enrichment

368. The State of Maryland (“Maryland”) re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

369. Had Mallinckrodt used the correct Base Date AMP for Acthar, Mallinckrodt would have been required to pay substantially larger rebates to Maryland. By retaining monies that were actually owed to Maryland under the MDRP, Mallinckrodt retained money that was the property of the Maryland Medicaid programs and to which it was not entitled.

370. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to Maryland pursuant to the MDRP had it used the correct Base Date AMP to calculate the amount of Medicaid rebates it owed for Acthar.

CLAIMS OF THE COMMONWEALTH OF MASSACHUSETTS

Count XLIX – False or Fraudulent Claim

(Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A, et seq.)

371. The Commonwealth of Massachusetts realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

372. Mallinckrodt was aware of its obligation under the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, to make or use truthful records or statements regarding its Base Date AMP for Acthar.

373. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly made or caused to be made false records or statements material to a false or fraudulent claim to the United States and Massachusetts relating to its Base Date AMP for Acthar which caused Massachusetts to receive substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

374. The Massachusetts Medicaid program is jointly funded by the United States and the Commonwealth of Massachusetts. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Massachusetts Medicaid rebates for Acthar, the United States and the Commonwealth of Massachusetts have incurred significant financial losses.

375. By virtue of Mallinckrodt's conduct, the Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count L – Reverse False Claims
(Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A, et seq.)

376. The Commonwealth of Massachusetts realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

377. Mallinckrodt was aware of its obligation under the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, to make or use truthful records or statements regarding its Base Date AMP for Acthar.

378. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt

knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts or a political subdivision thereof.

379. For each unit of Acthar the Massachusetts Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Massachusetts Medicaid rebate obligation by millions of dollars.

380. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the Massachusetts Medicaid program.

381. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Massachusetts Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt

had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

382. Mallinckrodt knowingly made, or used or caused to be made or used, false records or statements regarding its Base Date AMP for Acthar in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Massachusetts Medicaid program.

383. The Massachusetts Medicaid program is jointly funded by the United States and the Commonwealth of Massachusetts. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Massachusetts Medicaid rebates for Acthar, the United States and the Commonwealth of Massachusetts has incurred significant financial losses.

384. By virtue of Mallinckrodt's conduct, the Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count LI – False or Fraudulent Claim
(Massachusetts Medicaid False Claims Act, Mass. Gen. Laws ch. 118E, §§ 40, 44)

385. The Commonwealth of Massachusetts realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

386. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly and willfully made or caused to be made false statements or representations to the United States and Massachusetts material to determining its rights to benefits or payments for Acthar. These statements or representations related to its Base Date AMP for Acthar which caused Massachusetts to receive substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

387. The Massachusetts Medicaid program is jointly funded by the United States and the Commonwealth of Massachusetts. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Massachusetts Medicaid rebates for Acthar, the United States and the Commonwealth of Massachusetts have incurred significant financial losses.

389. By virtue of Mallinckrodt's conduct, the Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages, including the costs of investigation and litigation in accordance with Mass. Gen. Laws, ch. 118E, § 44.

Count LII – Reverse False Claims
(Massachusetts Medicaid False Claims Act, Mass. Gen. Laws ch. 118E, §§ 40, 44)

390. The Commonwealth of Massachusetts realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

391. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly and willfully made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts or a political subdivision thereof.

392. For each unit of Acthar the Massachusetts Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Massachusetts Medicaid rebate obligation by millions of dollars.

393. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's

requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the Massachusetts Medicaid program.

394. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Massachusetts Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

395. Mallinckrodt knowingly made, or used or caused to be made or used, false records or statements regarding its Base Date AMP for Acthar in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Massachusetts Medicaid program. Having knowledge since no later than April 2016 that it was acting in defiance of requests for corrective action by CMS, Mallinckrodt's failure to disclose such information to the Massachusetts Medicaid program so that it could continue to grossly underpay its rebate obligation to the Massachusetts Medicaid program was in violation of Mass. Gen. Laws ch. 118E, § 40 (3). Though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the Massachusetts Medicaid program.

396. The Massachusetts Medicaid program is jointly funded by the United States and the Commonwealth of Massachusetts. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Massachusetts Medicaid rebates for Acthar, the United States and the Commonwealth of Massachusetts has incurred significant financial losses.

397. By virtue of Mallinckrodt's conduct, the Commonwealth of Massachusetts has suffered actual damages and is entitled to recover treble damages, including the costs of investigation and litigation in accordance with Mass. Gen. Laws, ch. 118E, § 44.

Count LIII – Common Law Fraud

398. The Commonwealth of Massachusetts realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

399. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the Commonwealth of Massachusetts and the United States of its Base Date AMP for Acthar.

400. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

401. Mallinckrodt intended that the Commonwealth of Massachusetts rely upon these material misrepresentations.

402. The Commonwealth of Massachusetts did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, from the first quarter of 2013 through the first quarter of 2020, the Commonwealth of Massachusetts received substantially smaller rebate payments than

it would have otherwise been entitled to receive if Mallinckrodt had accurately reported its Base Date AMP for Acthar.

403. As a result of Mallinckrodt's conduct, the Commonwealth of Massachusetts suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count LIV – Breach of Contract

404. The Commonwealth of Massachusetts realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

405. As discussed above, Mallinckrodt entered into a rebate contract with the United States. The Commonwealth of Massachusetts was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

406. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that contract by failing to accurately report its Base Date AMP for Acthar.

407. By virtue of this conduct, the Commonwealth of Massachusetts is thus entitled to damages and any other relief the Court deems appropriate.

Count LV – Unjust Enrichment

408. The Commonwealth of Massachusetts realleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

409. The Commonwealth of Massachusetts Medicaid program received substantially smaller Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely inflated its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to the Commonwealth of Massachusetts. By retaining monies that were actually owed to the Commonwealth of

Massachusetts under the Medicaid Drug Rebate Program, Mallinckrodt retained money that is the property of the Commonwealth of Massachusetts to which it was not entitled.

410. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that should have been paid to the Commonwealth of Massachusetts, pursuant to the Medicaid Drug Rebate Program, absent Mallinckrodt's false reporting of its Base Date AMP for Acthar.

411. As a result of Mallinckrodt's conduct, the Commonwealth of Massachusetts suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

CLAIMS OF THE STATE OF MICHIGAN

412. The State of Michigan re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein. In addition to the facts alleged above, Michigan also asserts the following examples of the Acthar claims and rebate underpayments that it received: On or about May 19, 2014, a claim for Acthar was submitted to the Michigan Medicaid Program for beneficiary B.E. The Program paid more than \$96,000 for this claim. The Program also paid more than \$96,000 for a claim for beneficiary C.R. and \$160,000 for a claim for beneficiary A.D. on May 27, 2014 and June 23, 2014, respectively. The Program anticipated receiving a substantial rebate for the more than 300 units billed to Michigan Medicaid during the second quarter of 2014. Instead of paying the rebate it owed, Mallinckrodt knowingly underpaid its obligation by a significant amount.

Count LVI – Reverse False Claims **(Michigan Medicaid False Claim Act, MCL 400.607(3))**

413. The State of Michigan re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

414. For each unit of Acthar the Michigan Medicaid Program purchased, Mallinckrodt

had an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, Mallinckrodt has knowingly made, used, and caused to be made and used false records and statements that it submitted to various governmental agencies falsely purporting that it owed substantially less rebate monies to the states, including Michigan, than it actually owed. These false records and statements were used to avoid and conceal from the government Mallinckrodt's true rebate liability. These false records and statements were also used to falsely decrease their rebate obligation to Michigan. As a result, Mallinckrodt has failed to pay the Michigan Medicaid Program millions of dollars in Acthar rebates.

415. Since no later than 2013, Mallinckrodt has known and intentionally underpaid these rebates.

416. The Michigan Medicaid Program is jointly funded by the United States and the State of Michigan. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Michigan Medicaid rebates for Acthar, the United States and the State of Michigan have incurred significant financial losses.

417. By virtue of Mallinckrodt's conduct, the State of Michigan has suffered actual damages and is therefore entitled to treble damages under the Michigan Medicaid False Claim Act, MCL 400.612(1) to be determined at trial, plus attorneys' fees, costs and a penalty of not less than \$5,000 and not more than \$10,000 for each violation.

Count LVII – Unjust Enrichment

418. The State of Michigan re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

419. The Michigan Medicaid Program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely reported its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to Michigan. By falsely reporting its Base Date AMP, Mallinckrodt was able to retain profits for Acthar and avoid paying monies owed to Michigan.

420. By retaining monies that were actually owed to Michigan under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of Michigan and to which it was not entitled.

421. By retaining the use and enjoyment of the monies that should have been paid to Michigan pursuant to the Medicaid Rebate Program, Mallinckrodt has been unjustly enriched, and is liable to account for and pay such amounts or the proceeds there from, which are to be determined at trial, to the State of Michigan.

CLAIMS OF THE STATE OF NEVADA

Count LVIII – Violation of the Nevada False Claims Act **(NRS 357.010, *et seq.*)**

422. The State of Nevada re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

423. The Nevada False Claims Act, NRS 357.040(1), imposes liability on any person who, with or without specific intent to defraud:

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim; (c) Has possession, custody or control of public property or money used or to be used by the State or a political subdivision and knowingly delivers or causes to be delivered to the State or a political subdivision less money or property than the amount of which the person has possession, custody or control ... (f) Knowingly 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 political subdivision; (g) Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or

transmit money or property to the State or political subdivision

424. For each unit of Acthar the Nevada Medicaid Program has purchased since 2013, Mallinckrodt was aware of its obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. Mallinckrodt also knew that by using Acthar's 2013 price as its Base Date AMP instead, it had improperly avoided and decreased the rebate amount paid to Nevada through the first quarter of 2020.

425. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward by refusing to take the corrective action CMS first requested and then directed it to take. To date, Mallinckrodt has taken no such corrective action and knowingly and improperly continues to avoid and decrease its rebate obligation to Nevada Medicaid and/or retain funds which should properly be returned to the State of Nevada.

426. To further facilitate its improper avoidance of its obligations under the Rebate Statute, Mallinckrodt refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR until forced to do so in June of 2020, knowing that when it did so, the Nevada Medicaid program would seek payment for the rebate amount based on the larger price difference and would also seek reimbursement for all prior underpayments resulting from Mallinckrodt's use of the 2013 Base Date AMP for Acthar.

427. Since Nevada Medicaid is jointly funded by the State of Nevada and the United States, Mallinckrodt's knowing failure to pay the correct amount of Medicaid rebates for Acthar

and/or improper retention of money identified as unpaid rebates for Acthar directly resulted in significant financial loss to the State of Nevada.

428. By virtue of Mallinckrodt's conduct, the State of Nevada has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count LIX – Breach of Contract

429. The State of Nevada re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

430. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Nevada was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt has a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

431. From the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt breached that agreement by failing to report the true and correct Base Date AMP for Acthar as required by the Rebate Agreement and instead using the 2013 Base Date AMP.

432. By virtue of this conduct, the State of Nevada is thus entitled to damages and any other relief the Court deems appropriate.

Count LX – Unjust Enrichment

433. The State of Nevada re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

434. If Mallinckrodt had not misrepresented the Base Date AMP for Acthar since 2013, Mallinckrodt would have been required to pay significantly larger rebates to the State of Nevada. By falsely reporting its Base Date AMP through the first quarter of 2020, Mallinckrodt was able

to retain profits for Acthar and avoid paying monies owed to Nevada.

435. By retaining monies that were actually owed to the State of Nevada under the Medicaid Rebate Program, Mallinckrodt retained that which was the property of Nevada and to which it was not entitled.

436. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that should have been paid to Nevada pursuant to the Medicaid Rebate Program and is liable to account for and pay such amounts or the proceeds there from, which are to be determined at trial, to the State of Nevada.

CLAIMS OF THE STATE OF NEW JERSEY

Count LXI – Reverse False Claims **(New Jersey False Claims Act, N.J.S.A. 2A:32C-1, *et seq.*)**

437. The State of New Jersey repeats and re-alleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

438. The New Jersey False Claims Act (“NJFCA”), N.J.S.A. 2A:32C-1, provides in relevant part:

A person commits an unlawful act, if the person:

- (a) Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantor, or other recipient of State funds, a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
- (c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State; ...
- (g) Knowingly 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.

439. Within the meaning of the New Jersey Statutes Annotated, “knowingly” means, with respect to information, that a person: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of

the truth or falsity of the information. N.J.S.A. 2A:32C-2. Further, “no proof of specific intent to defraud is required.” Id. at 2A:32C-2.

440. Under N.J.S.A. 2A:32C-3, a person shall be jointly or severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. § 3729 *et seq.*). This amount may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub.L.101-410, for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person:

- (a) Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantor, or other recipient of State funds, a false or fraudulent claim for payment or approval;
- (b) Knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
- (c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State; ...
- (g) Knowingly 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.

441. For each unit of Acthar that the New Jersey Medicaid Program purchased, Mallinckrodt knew of its obligation under the MDRP, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar’s 1990 price as its Base Date AMP. Mallinckrodt also knew that all participating states would rely on the rate reflected in its Base Date AMP submissions in the Medicaid DDR system because the United States used that figure to calculate the unit rebate amount. Consequently, Mallinckrodt deliberately and effectively decreased its Acthar rebate payment obligations to the State of New Jersey.

442. For every quarter since 2013 and continuing through the first quarter of 2020, Mallinckrodt knowingly provided false quarterly submissions to CMS by using Acthar’s 2013 price, rather than its 1990 price for its Base Date AMP. Mallinckrodt knowingly presented a false

or fraudulent record by misrepresenting Acthar's Base Date in support of its false or fraudulent claim for payment of reduced Acthar rebates, which resulted in a gross underpayment of its rebate obligations to the State of New Jersey.

443. For every quarter since 2013 and continuing through the first quarter of 2020, Mallinckrodt knowingly used the incorrect Base Date AMP to conceal, avoid, or decrease its obligation to pay or transmit the correct rebate payment for Acthar to the State of New Jersey.

444. For every quarter since 2013 and continuing through the first quarter of 2020, Mallinckrodt knowingly made, used, or caused to be made or used, false records or statements regarding its Base Date AMP for Acthar that are material to its obligation to pay or transmit money or property to the State of New Jersey Medicaid Program.

445. Since no later than April 2016, Mallinckrodt knew that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take.

446. Mallinckrodt did not correct the 1990 Base Date AMP for Acthar in the Medicaid DDR system until the beginning of the second quarter of 2020. Mallinckrodt knew that once it made this change, the invoices the New Jersey Medicaid program received each quarter for Acthar would reflect a much higher rebate amount and require reimbursement of all prior underpayments resulting from Mallinckrodt's improper use of the 2013 Base Date AMP. Despite Mallinckrodt's independent obligation under the Rebate Statute to pay the proper rebate amount, the company's

delay in updating the DDR system facilitated its improper avoidance and decreasing of that obligation.

447. The United States and New Jersey jointly fund the Medicaid program. Therefore, by virtue of Mallinckrodt's unlawful false or fraudulent conduct, New Jersey has suffered actual damages. Under the NJFCA, the State of New Jersey is therefore entitled to recover treble damages, plus a civil monetary penalty for each violation.

Count LXII – Common Law Fraud

448. The allegations in all of the preceding paragraphs are realleged as if fully set forth herein.

449. For every quarter since 2013 and continuing through the first quarter of 2020, Mallinckrodt knowingly made and or caused to be made, a false material misrepresentation regarding the Base Rate AMP and or its rebate obligations to the State of New Jersey and to the United States.

450. Through these knowingly false and material representations, Mallinckrodt intended to induce the State of New Jersey to act or refrain from acting.

451. For every quarter since 2013 and continuing through the first quarter of 2020, the State of New Jersey did in fact justifiably rely on Mallinckrodt's representations and omissions and suffered injury due to that reliance. The State of New Jersey received significantly lower rebate payments from Mallinckrodt than it was entitled to receive and would have received, but for Mallinckrodt's failure to submit true and accurate statements of Acthar's Base Date AMP.

452. By virtue of these actions or failures to act, Mallinckrodt remains liable to the State of New Jersey for damages and any other relief the Court deems appropriate.

Count LXIII – Breach of Contract

453. The allegations in all of the preceding paragraphs are realleged as if fully set forth herein.

454. As discussed in the Legal Framework, The Medicaid Drug Rebate Program section of this complaint, Mallinckrodt entered into a rebate contract with the United States.

455. The State of New Jersey was an intended third-party beneficiary of that contract.

456. Under the terms of the agreement, Mallinckrodt maintained a duty to, *inter alia*, accurately report Acthar's Base Date AMP.

457. For every quarter since 2013 and continuing through the first quarter of 2020, Mallinckrodt breached that contract by failing to report accurately Acthar's Base Date AMP.

458. By virtue of this conduct, Mallinckrodt is liable to the State of New Jersey for damages and any other relief this court deems appropriate.

Count LXIV – Unjust Enrichment

459. The allegations in all of the preceding paragraphs are realleged as if fully set forth herein.

460. For every quarter since 2013 and continuing through the first quarter of 2020, Mallinckrodt knowingly inflated Acthar's Base Date AMP submitted on quarterly statements to CMS.

461. If Mallinckrodt had not falsely inflated Acthar's Base Date AMP, Mallinckrodt would have been responsible for substantially higher rebate payments to the State of New Jersey.

462. By retaining funds actually owed to the State of New Jersey under the MDRP, Mallinckrodt retained money, property which belonged to the State of New Jersey, and to which Mallinckrodt was not entitled.

463. Mallinckrodt unjustly enriched itself by retaining the use and enjoyment of the funds owed to the State of New Jersey pursuant to the Medicaid Drug Rebatement Act. Consequently, Mallinckrodt must account for and pay such amounts or the proceeds therefrom, which sum will be determined at trial, to the State of New Jersey.

CLAIMS OF THE STATE OF NEW MEXICO

Count LXV

(New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 to -15)

464. The State of New Mexico re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

465. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

466. Through the acts described above, Mallinckrodt knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim as follows under A-E below.

467. Through the acts described above and below, Mallinckrodt conspired to (a) present, or caused to be presented, false or fraudulent claims and (b) make or used a false record or statement material to a false or fraudulent claim as follows under A – E below.

A. For each unit of Acthar the New Mexico Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013 but no later than through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has

avoided and decreased its New Mexico Medicaid rebate obligation by hundreds of thousands of dollars.

B. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, Mallinckrodt has taken no such corrective action and knowingly and improperly continues to avoid and decrease its rebate obligation to New Mexico Medicaid.

C. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying New Mexico Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. In particular, Mallinckrodt has retained for itself tens of millions of dollars that it should have paid in rebates to the New Mexico Medicaid Program. Medicaid rebates collected by New Mexico offset the overall cost of the New Mexico Medicaid program.

D. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of New Mexico, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to the State of New Mexico.

E. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods

from 2013 onward. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, Mallinckrodt has taken no such corrective action and continues to deliver or cause to be delivered less than all of the Medicaid rebates it owes for Acthar.

468. The New Mexico Medicaid program is jointly funded by the United States and the State of New Mexico. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of New Mexico have incurred significant financial losses.

469. By virtue of Mallinckrodt's conduct, the State of New Mexico has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count LXVI
(New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to -14)

470. The State of New Mexico re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

471. This is a claim for treble damages and penalties under the New Mexico Fraud Against Taxpayers Act.

472. Through the acts described above, Mallinckrodt knowingly, intentionally, and willfully violated the New Mexico Fraud Against Taxpayers Act.

473. By virtue of Mallinckrodt's conduct, the State of New Mexico has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

CLAIMS OF THE STATE OF NEW YORK

Count LXVII – Violation of the New York False Claims Act **(State Fin. Law § 189, *et seq.*)**

474. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

475. The New York False Claims Act ("NYFCA"), State Fin. Law § 189(1), provides, in pertinent part, that any person who:

(d) 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 . . . (g) 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; or (h) 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

shall be liable: (i) to the state for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, adjusted to be equal to the civil penalty allowed under the federal False Claims Act, 31 U.S.C. sec 3729, *et seq.*, as amended, as adjusted for inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus three times the amount of all damages, including consequential damages, which the state . . . sustains because of the act of that person.

476. The NYFCA defines the terms "knowing" and "knowingly" to mean that a person, with respect to information relating to a claim, "(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." State Fin. Law § 188(3).

477. For each unit of Acthar the New York Medicaid Program purchased, Mallinckrodt was aware of its obligation under the MDRP, 42 U.S.C. § 1396r-8, to pay quarterly rebates using

Acthar's 1990 price as its Base Date AMP. Mallinckrodt also knew that its Base Date AMP submissions in the Medicaid DDR system would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Mallinckrodt was obligated to pay to the States, including New York, for Acthar.

478. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt provided false quarterly submissions to CMS using its 2013 price as its Base Date AMP with respect to Acthar.

479. From the first quarter of 2013 and continuing through the present, by failing to reimburse the New York Medicaid Program for rebate amounts for Acthar that it has underpaid, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government and knowingly delivered, or caused to be delivered, less than all of that money or property.

480. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly made, used, or caused to be made or used, false records or statements regarding its Base Date AMP for Acthar that were material to its obligation to pay or transmit money or property to the New York Medicaid Program.

481. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly concealed or knowingly and improperly decreased its obligation to pay or transmit money or property to the New York Medicaid Program. By using Acthar's 2013 price as its Base Date AMP, Mallinckrodt improperly decreased its rebate obligation by paying a much lower rebate amount.

482. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's

requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the New York Medicaid Program.

483. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the New York Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

484. Since this program is jointly funded by New York and the United States, Mallinckrodt's conduct directly resulted in significant financial loss to the State of New York and the United States.

485. By virtue of the false or fraudulent claims, and/or false records or statements, Mallinckrodt made or caused to be made, the State of New York suffered damages and therefore is entitled to recover from Mallinckrodt treble damages under the NYFCA, in an amount to be proved at trial, plus a civil penalty for each violation.

Count LXVIII – Violation of New York Social Services Law
(N.Y. Soc. Serv. Law § 145-b)

486. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

487. N.Y. Soc. Serv. Law § 145-b provides, in pertinent part, that:

It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

488. As set forth above, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, made or used false statements or misrepresentations regarding its Base Date AMP for Acthar in order to conceal, avoid, or decrease its obligation to pay or transmit money or property to the New York Medicaid Program. In so doing, Mallinckrodt improperly obtained or attempted to obtain payment from the Medicaid Program.

489. By reason of the foregoing, Mallinckrodt is liable, pursuant to N.Y. Soc. Serv. Law § 145-b, to the State of New York for treble damages, penalties, and costs.

Count LXIX – Repeated and Persistent Fraud
(New York Executive Law, N.Y. Exec. Law § 63(12))

490. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

491. N.Y. Executive Law § 63(12) makes “repeated fraudulent . . . acts or . . . persistent fraud . . . in the carrying on, conducting or transaction of business” actionable by the Attorney General of the State of New York.

492. By engaging in the acts and practices described above, Mallinckrodt has engaged in repeated fraudulent acts or persistent fraud in violation of N.Y. Executive Law § 63(12).

493. By reason of the foregoing, Mallinckrodt is liable to the State of New York for damages in an amount to be determined at trial.

Count LXX – Repeated and Persistent Illegal Conduct
(New York Executive Law, N.Y. Exec. Law § 63(12))

494. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

495. N.Y. Executive Law § 63(12) makes “repeated . . . illegal acts or . . . persistent . . . illegality in the carrying on, conducting or transaction of business” actionable by the Attorney General of the State of New York.

496. Mallinckrodt’s violations of the New York False Claims Act, State Fin. Law § 189(1), and N.Y. Social Services Law § 145-b constitute repeated and persistent illegal conduct in violation of N.Y. Executive Law § 63(12).

497. By engaging in the acts and practices described above, Mallinckrodt has engaged in repeated illegal acts or persistent illegal conduct in violation of N.Y. Executive Law § 63(12).

498. By reason of the foregoing, Mallinckrodt is liable to the State of New York for damages, in an amount to be determined at trial.

Count LXXI – Violation of New York Executive Law
(N.Y. Exec. Law § 63-c)

499. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

500. The acts and practices of Mallinckrodt complained of herein constitute a misappropriation of public property, in violation N.Y. Exec. Law § 63-c.

501. By reason of the foregoing, the State of New York is entitled to restitution from Mallinckrodt in an amount yet to be determined, but at least in the amount of the illegally retained and obtained Medicaid funds, plus the maximum amount of interest available under law.

Count LXXII – Common Law Fraud

502. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

503. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and the State of New York of its Base Date AMP for Acthar.

504. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

505. Mallinckrodt intended that New York act or refrain from acting in justifiable reliance on these misrepresentations.

506. New York did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, between 2013 through the first quarter of 2020, New York received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

507. As a result of Mallinckrodt's conduct, the State of New York suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count LXXIII – Breach of Contract

508. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

509. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of New York was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

510. For the reasons discussed above, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

511. By virtue of this conduct, New York is thus entitled to damages and any other relief the Court deems appropriate.

Count LXXIV – Unjust Enrichment

512. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

513. The New York Medicaid program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely inflated its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to New York. By retaining monies that were actually owed to New York under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of New York and to which it was not entitled.

514. By retaining the use and enjoyment of the monies that should have been paid to New York pursuant to the Medicaid Rebate Program, Mallinckrodt has been unjustly enriched,

and is liable to account for and pay such amounts or the proceeds therefrom, which are to be determined at trial, to the State of New York.

Count LXXV – Disgorgement

515. The State of New York repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

516. Mallinckrodt failed to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement and retained money that should have been paid to the States, including the State of New York.

517. This Court has the equitable power to order defendant Mallinckrodt to disgorge the entire amount of improperly-retained rebate payments that should have been paid to the States.

518. New York seeks disgorgement of all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement.

CLAIMS OF THE STATE OF NORTH CAROLINA

Count LXXVI – Reverse False Claims
(North Carolina False Claims Act, Article 51, N.C.G.S. §1-607(a)(7))

519. North Carolina re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

520. For each unit of Acthar the North Carolina Medicaid program purchased, Mallinckrodt was aware of its obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly concealed, and knowingly and improperly avoided or decreased this obligation to pay or transmit money or property to the State of North Carolina by paying a much lower rebate amount, using Acthar's 2013 price as its Base

Date AMP instead. In this manner, Mallinckrodt knowingly concealed and knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the State of North Carolina by decreasing its North Carolina Medicaid rebate obligation by millions of dollars.

522. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to North Carolina Medicaid.

523. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the North Carolina Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

524. The North Carolina Medicaid program is jointly funded by the United States and North Carolina. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, North Carolina has incurred significant financial losses.

525. By virtue of Mallinckrodt's conduct, North Carolina has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count LXXVII – Conversion
(North Carolina False Claims Act, Article 51, N.C.G.S. §1-607(a)(4))

526. North Carolina re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

527. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying North Carolina Medicaid rebates for Acthar for the first quarter of 2013 through the first quarter of 2020, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to North Carolina. Medicaid rebates collected by North Carolina offset the overall costs of the North Carolina Medicaid program.

528. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by North Carolina, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from the first quarter of 2013 through the first quarter of 2020 for Acthar, to North Carolina.

529. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from the first quarter of 2013 through the first quarter of 2020. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, though

Mallinckrodt has corrected its Base Date AMP, it continues to deliver or cause to be delivered less than all of the Medicaid rebates it owes for Acthar.

530. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that, if it did so, the North Carolina Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's refusal to update the DDR system further caused the company to deliver less than the proper rebate amounts to North Carolina Medicaid.

531. By virtue of Mallinckrodt's conduct, North Carolina has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count LXXVIII – Unjust Enrichment

532. North Carolina re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

533. If Mallinckrodt had not used the incorrect Base Date AMP for Acthar for the first quarter of 2013 through the first quarter of 2020, Mallinckrodt would have been required to pay substantially larger rebates to North Carolina. By retaining monies that were actually owed to North Carolina under the MDRP, Mallinckrodt retained money that was the property of the North Carolina Medicaid programs and to which it was not entitled.

534. Mallinckrodt received unjust enrichment when it:

- a. Received a measurable benefit conferred on it by North Carolina;

- b. Consciously accepted the benefit conferred; and
- c. The benefit was not conferred officiously or gratuitously.

535. As a direct and proximate result of Mallinckrodt's actions, and as a direct and proximate result of retaining monies that were actually owed to North Carolina under the MDRP, Mallinckrodt realized the value of said monies for itself, and retained the benefit of the same for itself. By receiving and retaining monies that actually belonged to North Carolina, and/or otherwise receiving and retaining the benefit of North Carolina's monies, Mallinckrodt received and retained money that is the property of North Carolina to which Defendant was not entitled. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to North Carolina pursuant to the MDRP had it used the correct Base Date AMP from the first quarter of 2013 through the first quarter of 2020 to calculate the amount of Medicaid rebates it owed for Acthar. North Carolina is entitled to the return of these monies.

Count LXXIX – Disgorgement

536. North Carolina repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

537. Mallinckrodt failed to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement and retained money that should have been paid to the States, including North Carolina.

538. This Court has the equitable power to order defendant Mallinckrodt to disgorge the entire amount of improperly-retained rebate payments that should have been paid to the States.

539. North Carolina seeks disgorgement of all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement.

Count LXXX – Common Law Fraud

540. North Carolina repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

541. The false statements made by Mallinckrodt from the first quarter of 2013 through the first quarter of 2020, as further described in the paragraphs above, were misrepresentations and/or concealments it had a duty to disclose of past or existing material facts.

542. These misrepresentations and/or concealments were reasonably calculated to deceive North Carolina, including its Medicaid Program.

543. Mallinckrodt made these misrepresentations and/or concealments with knowledge of their falsity and/or with reckless disregard for their truth.

544. Mallinckrodt made these misrepresentations and/or concealments intending that North Carolina would reasonably rely on their accuracy.

545. North Carolina reasonably and justifiably relied upon the Mallinckrodt's misrepresentations and/or concealments.

546. Mallinckrodt gained increased revenue, and retained money that should have been paid to the States, including North Carolina, based on its misrepresentations and/or concealments.

547. Through the acts described above, Defendant has perpetuated a fraud and deceit upon North Carolina and, as a result, has directly and proximately caused damages to North Carolina.

CLAIMS OF THE STATE OF OKLAHOMA

Count LXXXI – Reverse False Claims
(Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053.1(B)(7))

548. The State of Oklahoma re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

549. For each unit of Acthar the Oklahoma Medicaid Program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Oklahoma Medicaid rebate obligation by millions of dollars in violation of the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053.1(B)(7).

550. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the Oklahoma Medicaid Program.

551. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Oklahoma Medicaid Program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

552. The Oklahoma Medicaid Program is jointly funded by the United States and the State of Oklahoma. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the State of Oklahoma has incurred significant financial losses.

553. By virtue of Mallinckrodt's conduct, the State of Oklahoma has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count LXXXII – Conversion
(Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053.1(B)(4))

554. The State of Oklahoma re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

555. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Oklahoma Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government in violation of Okla. Stat. tit. 63 § 5053.1(B)(4). In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to the State of Oklahoma. Medicaid rebates collected by the State of Oklahoma offset the overall costs of the Oklahoma Medicaid Program.

556. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of Oklahoma, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 forward for Acthar, to the State of Oklahoma.

557. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 through the first quarter of 2020. Mallinckrodt understood that CMS's requested corrective action

meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it continues to avoid its rebate obligation to the Oklahoma Medicaid Program.

558. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that, if it did so, the Oklahoma Medicaid Program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's refusal to update the DDR system further caused the company to deliver less than the proper rebate amounts to the Oklahoma Medicaid Program.

559. By virtue of Mallinckrodt's conduct, the State of Oklahoma has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count LXXXIII – Violation of the Oklahoma Medicaid Program Integrity Act
(Okla. Stat. tit. 56 §§ 1005-1007)

560. The State of Oklahoma repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

561. By virtue of the above acts, Mallinckrodt willfully and knowingly made or caused to be made false or fraudulent claims, by omission or commission, to the State of Oklahoma and/or

the Oklahoma Medicaid Program for payment or approval in violation of the Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56 §§1005(A)(1).

562. As a result of Mallinckrodt's refusal to report the correct base date, Mallinckrodt willfully and knowingly made or caused to be made statements or omissions that were material to false or fraudulent claims to the State of Oklahoma. The false records or statements, by omission or commission, were Mallinckrodt's Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that, if it did so, the Oklahoma Medicaid Program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's refusal to update the DDR system further caused the company to deliver less than the proper rebate amounts to the Oklahoma Medicaid Program.

563. By virtue of Mallinckrodt's conduct the State of Oklahoma is entitled to damages, restitution, civil monetary fines and penalties, investigative costs, litigation costs, attorney fees, and interest, and any other damages, penalties, or fines, as provided for in Okla. Stat. tit. 56 § 1007.

Count LXXXIV – Common Law Fraud

564. The State of Oklahoma repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

565. From the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and the State of Oklahoma of its Base Date AMP for Acthar.

566. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual

knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

567. Mallinckrodt intended that the State of Oklahoma act or refrain from acting in justifiable reliance on these misrepresentations.

568. The State of Oklahoma did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, between 2013 through present, the State of Oklahoma received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

569. By virtue of this conduct, Mallinckrodt is liable to the State of Oklahoma for actual damages plus prejudgment interest, punitive damages pursuant to Okla. Stat. tit. 23, § 9.1, and any other relief the Court deems appropriate.

Count LXXXV – Breach of Contract

570. The State of Oklahoma repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

571. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Oklahoma was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

572. For the reasons discussed above, from the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt materially failed in its performance and breached that agreement by failing to accurately report its Base Date AMP for Acthar.

573. By virtue of this conduct, the State of Oklahoma is thus entitled to damages and any other relief the Court deems appropriate.

Count LXXXVI – Unjust Enrichment

574. The State of Oklahoma repeats and re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

575. If Mallinckrodt had not used the incorrect Base Date AMP for Acthar since January 1, 2013, Mallinckrodt would have been required to pay substantially larger rebates to the State of Oklahoma. By retaining monies that were actually owed to the State of Oklahoma under the MDRP, Mallinckrodt retained money that was the property of the Oklahoma Medicaid Program and to which it was not entitled.

576. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to the State of Oklahoma pursuant to the MDRP had it used the correct Base Date AMP to calculate the amount of Medicaid rebates it owed for Acthar.

577. By directly or indirectly retaining funds from the State of Oklahoma which Mallinckrodt was not entitled, and to the State of Oklahoma's detriment, Mallinckrodt has been unjustly enriched and is liable to account for and pay such amounts, or the proceeds therefrom, in restitution or disgorgement, all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement to the State of Oklahoma, plus costs, expenses, and the maximum amount of interest available under law.

CLAIMS OF THE COMMONWEALTH OF PUERTO RICO

Count LXXXVII – Reverse False Claims
(P.R. Laws Ann. Tit 32, § 2934(1)(d))

572. The Commonwealth of Puerto Rico re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

573. For each unit of Acthar the Puerto Rico Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using

Acthar's 1990 price as its Base Date AMP. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Puerto Rico Medicaid rebate obligation by millions of dollars.

574. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the Puerto Rico Medicaid Program.

575. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Puerto Rico Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

576. The Puerto Rico Medicaid program is jointly funded by the United States and the Commonwealth of Puerto Rico. As a result of Mallinckrodt's knowing and improper failure to pay

the correct amount of Puerto Rico Medicaid rebates for Acthar, the United States and the Commonwealth of Puerto Rico has incurred significant financial losses.

577. By virtue of Mallinckrodt's conduct, the Commonwealth of Puerto Rico has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty of not less than \$11,181 but not more than \$22,363 for each instance of unlawful conduct from the date the dispositions contained in Chapter IV of the "False Claims to Government of Puerto Rico Programs, Contracts, and Services Act" came into effect on January 23rd, 2019. (Public Law No. 154 of July 23rd, 2018).

Count LXXXVIII – Unjust Enrichment

578. The Commonwealth of Puerto Rico re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

579. The Puerto Rico Medicaid Program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely reported its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to the Commonwealth of Puerto Rico. By falsely reporting its Base Date Amp, Mallinckrodt was able to retain profits for Acthar and avoid paying monies owed to the Commonwealth of Puerto Rico.

580. By retaining monies that were actually owed to the Commonwealth of Puerto Rico under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of the Commonwealth of Puerto Rico and to which it was not entitled.

581. By retaining the use and enjoyment of the monies that should have been paid to the Commonwealth of Puerto Rico pursuant to the Medicaid Rebate Program, Mallinckrodt has been

unjustly enriched, and is liable to account for and pay such amounts or the proceeds there from, which are to be determined at trial, to the Commonwealth of Puerto Rico.

Count LXXXIX – Breach of Contract

582. The Commonwealth of Puerto Rico re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

583. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The Commonwealth of Puerto Rico was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

584. For the reasons discussed above, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

585. By virtue of this conduct, the Commonwealth of Puerto Rico is thus entitled to damages and any other relief the Court deems appropriate.

CLAIMS OF THE STATE OF RHODE ISLAND

Count XC – Common Law Fraud

586. The State of Rhode Island repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

587. From the first quarter of 2013 and continuing through the present, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and the State of Rhode Island of its Base Date AMP for Acthar.

588. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual

knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

589. Mallinckrodt intended that The State of Rhode Island act or refrain from acting in justifiable reliance on these misrepresentations.

590. The State of Rhode Island did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, between 2013 through present, Rhode Island received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

591. As a result of Mallinckrodt's conduct, the State of Rhode Island suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count XCI – Breach of Contract

592. The State of Rhode Island repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

593. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Rhode Island was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

594. For the reasons discussed above, from the first quarter of 2013 and continuing through the present, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

595. By virtue of this conduct, the State of Rhode Island is thus entitled to damages and any other relief the Court deems appropriate.

Count XCII – Unjust Enrichment

596. The State of Rhode Island re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

597. If Mallinckrodt had not used the incorrect Base Date AMP for Acthar since January 1, 2013, Mallinckrodt would have been required to pay substantially larger rebates to the State of Rhode Island. By retaining monies that were actually owed to the State of Rhode Island under the MDRP, Mallinckrodt retained money that was the property of the State of Rhode Island Medicaid programs and to which it was not entitled.

598. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to the State of Rhode Island pursuant to the MDRP had it used the correct Base Date AMP to calculate the amount of Medicaid rebates it owed for Acthar.

Count XCIII – Violation of Rhode Island False Claims Act
(R.I. Gen. Laws §§ 9-1.1-1, *et seq.*)

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

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

601. The Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a), creates liability for any person who, *inter alia*:

- (1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or

(7) 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.

602. Mallinckrodt has violated each of these provisions of the Rhode Island FCA.

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

CLAIMS OF THE STATE OF TENNESSEE

Count XCIV – Reverse False Claims **(Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(D))**

604. The State of Tennessee (“Tennessee”) re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

605. For each unit of Acthar the Tennessee Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar’s 1990 price as its Base Date AMP. For every quarter from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar’s 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Tennessee Medicaid rebate obligation by tens of millions of dollars.

606. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS’s requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it

would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to Tennessee Medicaid.

607. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Tennessee Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

608. The Tennessee Medicaid program is jointly funded by the United States and Tennessee. As a result of Mallinckrodt's misleading and concealing statements used to decrease its obligation to reimburse TennCare for Acthar purchases, the State of Tennessee has incurred significant financial losses in violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(D).

609. By virtue of Mallinckrodt's conduct, Tennessee has suffered actual damages and is entitled to recover to treble damages plus a civil monetary penalty of \$5,000 to \$25,000 per violation. Tenn. Code Ann. § 71-5-182(a)(1)(D).

Count XCV – Common Law Fraud

610. Tennessee repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

611. From the first quarter of 2013 and continuing until the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and Tennessee of its Base Date AMP for Acthar.

612. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

613. Mallinckrodt intended that Tennessee act or refrain from acting in justifiable reliance on these misrepresentations.

614. Tennessee did, in fact rely upon Mallinckrodt's fraudulent misrepresentations. As a result, Tennessee received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

615. As a result of Mallinckrodt's conduct, Tennessee suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count XCVI – Breach of Contract

616. Tennessee repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

617. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. Tennessee was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

618. For the reasons discussed above, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

619. By virtue of this conduct, Tennessee is thus entitled to damages and any other relief the Court deems appropriate.

Count XCVII – Unjust Enrichment

620. Tennessee repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

621. If Mallinckrodt had not used the incorrect Base Date AMP for Acthar, Mallinckrodt would have been required to pay substantially larger rebates to Tennessee. By retaining monies that were actually owed to Tennessee under the MDRP, Mallinckrodt retained money that was the property of the Tennessee Medicaid programs and to which it was not entitled.

622. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of the monies that it should have paid to Tennessee pursuant to the MDRP had it used use the correct Base Date AMP to calculate the amount of Medicaid rebates it owed for Acthar.

Count XCVIII – Disgorgement

623. Tennessee repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

624. Mallinckrodt failed to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement and retained money that should have been paid to the States, including the Tennessee.

625. This Court has the equitable power to order defendant Mallinckrodt to disgorge the entire amount of improperly-retained rebate payments that should have been paid to the States.

626. Tennessee seeks disgorgement of all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement.

CLAIMS OF THE STATE OF TEXAS

627. The State of Texas ("Texas") repeats and realleges the allegations from every preceding paragraph as if fully set forth herein. Texas also alleges the following:

628. The Texas Vendor Drug Program ("VDP") of the Texas Health and Human Services Commission administers the pharmaceutical drug benefit for the Texas Medicaid program. Texas Medicaid pays reimbursement claims to pharmacy providers only for drugs that are listed on the Texas Medicaid formulary known as the Texas Drug Code Index ("TDCI"). 1 Tex. Admin. Code § 354.1831 (2019). To enroll a drug on the TDCI, a manufacturer must have a valid rebate agreement with CMS. *Id.* § 354.1921(a). The manufacturer must then file and have VDP approve a certified application (the "Texas Application") for each drug it wants enrolled on the TDCI. *Id.* § 354.1921(b).

629. Questcor submitted a Texas Application for Acthar with NDC 63004-7731-01 to VDP on July 13, 2002. Exhibit 29 at 4-6. Questcor attached a copy of the FDA's approval letter for NDA 8372 with that application. *Id.* at 7. VDP approved the application on July 22, 2002. *Id.* at 4 (noting the approval date in handwriting on the upper right corner of the page).

630. When Questcor started reporting a new NDC for Acthar to CMS' DDR system in January 2013, pharmacies in Texas complained to Texas Medicaid that they were not being reimbursed by VDP for Acthar. Exhibit 30 at 2-3, Jerry Rodriguez email to Marily Cuthill at Questcor regarding Acthar NDC Change (Feb. 4, 2013). VDP requested information about Acthar's new NDC and pricing from Questcor in order to enroll the drug on the TDCI and make it eligible for reimbursement by Texas Medicaid. *Id.* Questcor provided that information on

February 6, 2013, when it submitted another Texas Application for Acthar, this time under the new NDC 63004-8710-1. Exhibit 31 at 2-6.

631. In its communications with VDP, Questcor acknowledged that Acthar was approved under NDA 008372 and that the IS indication was approved under sNDA 22432. Specifically, in response to question eight on the Texas Application that asked whether the drug was “now marketed under an approved NDA or ANDA,” Questcor indicated that the drug was approved under both NDA “3,872 [sic] and 22,432” and attached both the FDA’s “Original 1952 approval letter” for NDA 8372 and the “[FDA] Action letter from 2010 for IS approval” under sNDA 22432. Exhibit 31 at 5, 7-11, 40.

632. By submitting the Texas Application to VDP, Questcor certified that the information on the application was “correct” and that the product was not in violation of Federal or state law. *Id.* at 6.

The Texas Medicaid Fraud Prevention Act

633. To target fraud against the Texas Medicaid program and protect its integrity, the Texas Medicaid Fraud Prevention Act (“TMFPA”) grants the Attorney General of Texas with authority to investigate and pursue actions against persons who commit certain unlawful acts prohibited by the statute. Tex. Hum. Res. Code Ann. ch. 36 (West 2015). The TMFPA permits Texas to recover civil remedies and civil penalties for fraud associated with unlawful acts and imposes administrative sanctions such as suspension from Texas Medicaid. *Id.* §§ 36.052, 36.005(b).

634. While the TMFPA and FCA share similar objectives, the TMFPA differs from the FCA in two important ways: (1) the TMFPA defines “unlawful acts” that are actionable and (2) the TMFPA permits the state to recover civil remedies and civil penalties rather than “damages.”

See In re Xerox, 555 S.W.3d 518, 526-535 (Tex. 2018) (discussing the relevant provision under the heading “The Remedies in section 36.052 Are Not Damages”).

635. A person is liable under the TMFPA if the person commits certain unlawful acts, many of which are not conditioned on the person’s submission of a claim for payment to Texas Medicaid. Rather, a person commits an unlawful act when the person:

- knowingly makes, or causes or induces the making of a false statement of material fact about information required by state or federal law regarding the Medicaid program, or
- knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money to Texas under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money to Texas under the Medicaid program.

Tex. Hum. Res. Code Ann. § 36.002(4)(B), (12).

636. A person acts “knowingly” with respect to information if the person (i) has actual knowledge of the information; (ii) acts with conscious indifference to the truth or falsity of the information, or (iii) acts in reckless disregard of the truth or falsity of the information. *Id.* at § 36.0011(a)(1)-(3). The TMFPA does not require Texas to prove that Mallinckrodt acted with specific intent to commit an unlawful act in order to prove that Mallinckrodt acted knowingly. *Id.* at § 36.0011(b).

637. An “obligation” is “a duty that arises from statute or regulation. *Id.* at § 36.001(7-a)(C).

638. A fact or information is “material” if it has “a natural tendency to influence or [is] capable of influencing.” *Id.* at § 36.001(5-a). Unlike the FCA, a fact or information does not have

to be tied to “the payment or receipt of money or property” in order to be material under the TMFPA. *Compare* Tex. Hum. Res. Code Ann. § 36.001(5-a), *with* 31 U.S.C. § 3729(b)(4).

639. Unlike the FCA, the TMFPA allows Texas to recover civil remedies and penalties, not “damages.” *See Xerox*, 555 S.W.3d at 526-535 (reasoning that the remedies under section 36.052 are not damages because they are “fixed without regard to any loss to the Medicaid program and without a direct benefit to the liable party”). The remedies include the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party; two times the amount of the payment or the value of the benefit described above; interest on the amount of the payment or the value of the benefit described above; and a civil penalty. Tex. Hum. Res. Code Ann. § 36.052(a).

Count XCIX – Making and Inducing False Statements About Information Required by
Law
(Tex. Hum. Res. Code § 36.002(4)(B))

640. Texas realleges and incorporates by reference every preceding paragraph of this complaint set out above as if fully set forth herein.

641. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt committed unlawful acts when it knowingly made, or caused or induced the making of a false statement of material fact about information required by state or federal law regarding the Medicaid program. *See* Tex. Hum. Res. Code § 36.002(4)(B).

642. Specifically, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly reported a 2013 Base Date AMP for Acthar (information the Rebate Statute required Mallinckrodt to report) to the Medicaid DDR instead of the 1990 Base Date AMP. Throughout that time, Mallinckrodt knew that (1) CMS used the Base Date AMP for Acthar in the

Medicaid DDR to calculate a URA; (2) CMS sent the URA to Texas Medicaid so that Texas Medicaid could calculate and submit Medicaid Rebate invoices to Mallinckrodt; and thus (3) Mallinckrodt could report the 2013 Base Date AMP for Acthar rather than the 1990 Base Date AMP to decrease the Medicaid Rebate payments it owed Texas Medicaid.

643. Also, although Mallinckrodt knew that it was not entitled to use a 2013 Base Date AMP for Acthar, Mallinckrodt nonetheless knowingly misled VDP when it certified on its January 2013 Texas Application for Acthar that “the product was not in violation of Federal or state law.” Exhibit 31 at 6. Texas law required Mallinckrodt to submit the Texas Application so that Acthar would be enrolled on the TDCI and made eligible for reimbursement by Texas Medicaid. 1 Tex. Admin. Code § 354.1921(b).

644. Despite CMS’ repeated requests for Mallinckrodt to use the 1990 Base Date AMP—which Mallinckrodt’s own regulatory department agreed was Acthar’s proper Base Date AMP—and the D.C. District Court’s March 2020 ruling that affirmed CMS’ determination, Mallinckrodt continues to report the 2013 Base Date AMP for Acthar to the Medicaid DDR.

645. Thus, in January 2013, Mallinckrodt knowingly made false statements on the Texas Application to VDP about Acthar’s product status; and from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly made false statements about Acthar’s Base Date AMP to the Medicaid DDR and knowingly caused CMS to send Texas Medicaid a URA based on that false Base Date AMP.

646. Since the United States and Texas jointly fund the Texas Medicaid program, both the United States and Texas have incurred significant financial losses as a result of Mallinckrodt’s knowing and improper effort to avoid and decrease the amount of Medicaid rebates it paid for Acthar.

Count C – False Statements to Decrease an Obligation to Pay
(Tex. Hum. Res. Code § 36.002(12))

647. Texas realleges and incorporates by reference every preceding paragraph of this complaint set out above as if fully set forth herein.

648. From the first quarter of 2013 through the first quarter of 2020, Mallinckrodt committed unlawful acts when it knowingly made, used, or caused the making or use of a false record or statement material to an obligation to pay or transmit money to Texas under the Medicaid program, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to Texas under the Medicaid program. *See* Tex. Hum. Res. Code § 36.002(12).

649. Specifically, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly concealed the 1990 Base Date AMP for Acthar when it reported Acthar's Base Date AMP—information material to CMS and Texas Medicaid's calculation of Medicaid rebates Mallinckrodt owed Texas Medicaid. Instead, Mallinckrodt knowingly reported a 2013 Base Date AMP for Acthar to the Medicaid DDR. Throughout that time, Mallinckrodt knew that (1) CMS used the Base Date AMP for Acthar in the Medicaid DDR to calculate a URA; (2) CMS sent the URA to Texas Medicaid so that Texas Medicaid could submit Medicaid Rebate invoices to Mallinckrodt; and thus (3) Mallinckrodt could report the 2013 Base Date AMP for Acthar rather than the 1990 Base Date AMP to decrease the Medicaid Rebate payments it owed Texas Medicaid.

650. Despite CMS' repeated requests for Mallinckrodt to use the 1990 Base Date AMP—which Mallinckrodt's own regulatory department agreed was Acthar's proper Base Date AMP—and the D.C. District Court's March 2020 ruling that affirmed CMS' determination, Mallinckrodt continues to report the 2013 Base Date AMP for Acthar to the Medicaid DDR.

651. Thus, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt knowingly reported a false Base Date AMP for Acthar to the Medicaid DDR and knowingly concealed Acthar's actual Base Date AMP from CMS in order to decrease its Medicaid rebate payments to Texas Medicaid.

652. Since the United States and Texas jointly fund the Texas Medicaid program, both the United States and Texas have incurred significant financial losses as a result of Mallinckrodt's knowing and improper effort to avoid and decrease the amount of Medicaid rebates it paid for Acthar.

Civil Remedies Under the TMFPA for Counts XCIX-C

653. Under the TMFPA, a person who commits an unlawful act is liable to the State of Texas for: (1) the amount of any payment provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including payments to third parties, (2) interest on the amount of the payment, (3) two times the amount of the payment, (4) a civil penalty for each unlawful act, and (5) the fees, expenses, and costs the Attorney General reasonably incurred in investigating and obtaining civil remedies in this matter. Tex. Hum. Res. Code Ann. §§ 36.052, 36.007, 36.110(c).

654. Texas will seek an amount as civil penalties that will be justified and appropriate under the facts and the law.

655. A defendant who commits an unlawful act may not supply or sell a product under the Texas Medicaid program for ten years. *Id.* at § 36.005(b).

656. Texas invokes in the broadest sense all relief possible under the TMFPA whether specified in this pleading or not.

For these reasons, Texas respectfully requests this Court to enter judgment for Texas and against Mallinckrodt for Counts XCIX – C of this complaint and impose the following civil remedies and civil penalties:

1. Texas requests that judgment be entered upon trial of this case in favor of the States and the Relator against Mallinckrodt to the maximum extent allowed by law.
2. Texas asks that it recover from Mallinckrodt under the TMFPA:
 - a. the value of any payments or any monetary or in-kind benefits provided under the Texas Medicaid program, directly or indirectly, as a result of Mallinckrodt's unlawful acts;
 - b. interest on the value in 2.a.;
 - c. civil penalties in an amount not less than \$5,500.00 or more than \$11,000.00 or the maximum amount imposed as provided by 31 U.S.C. section 3729(a), if that amount exceeds \$11,000, for each unlawful act Mallinckrodt committed;
 - d. two times the value in 2.a.; and
 - e. attorneys' fees, expenses, and costs.

Id. at §§ 36.052, 36.007.
3. Once the Court enters judgment for any civil remedies or civil penalties, Texas requests that a lien attach to all of Mallinckrodt's property and assets until the judgment is satisfied.
4. Texas also asks for other relief at law or in equity which it may show it is entitled to.

CLAIMS OF THE STATE OF VERMONT

Count CI – Violation of the Vermont False Claims Act **(32 V.S.A. § 630, *et seq.*)**

657. The State of Vermont repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

658. The Vermont False Claims Act, 32 V.S.A. § 631(a), provides, in pertinent part, that no person shall:

(5) 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 . . . (9) 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; (10) knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the State[.]

Pursuant to 32 V.S.A. § 631(b), any person who violates a provision of subsection (a) of this section shall be liable to the State for:

(1) a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each act constituting a violation of subsection (a) of this section, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461); (2) three times the amount of damages that the State sustains because of the act of that person; and (3) the costs of the investigation and prosecution of such violation.

659. The Vermont False Claims Act defines the terms “knowing” and “knowingly” to 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) requires no proof of specific intent to defraud.” 32 V.S.A. § 630(2).

660. For each unit of Acthar the Vermont Medicaid Program purchased, Mallinckrodt was aware of its obligation under the MDRP, 42 U.S.C. § 1396r-8, to pay quarterly rebates using

Acthar's 1990 price as its Base Date AMP. Mallinckrodt also knew that its Base Date AMP submissions in the Medicaid DDR system would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Mallinckrodt was obligated to pay to the States, including Vermont, for Acthar.

661. From the first quarter of 2013 and through the first quarter of 2020, Mallinckrodt provided false quarterly submissions to CMS using its 2013 price as its Base Date AMP with respect to Acthar.

662. From the first quarter of 2013 and continuing through the present, by failing to reimburse the Vermont Medicaid Program for rebate amounts for Acthar that it has underpaid, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government and knowingly delivered, or caused to be delivered, less than all of that money or property.

663. From the first quarter of 2013 and through the first quarter of 2020, Mallinckrodt knowingly made, used, or caused to be made or used, false records or statements regarding its Base Date AMP for Acthar that were material to its obligation to pay or transmit money or property to the Vermont Medicaid Program.

664. From the first quarter of 2013 and through the first quarter of 2020, Mallinckrodt knowingly concealed or knowingly and improperly decreased its obligation to pay or transmit money or property to the Vermont Medicaid Program. By using Acthar's 2013 price as its Base Date AMP, Mallinckrodt improperly decreased its rebate obligation by paying a much lower rebate amount.

665. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's

requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid its rebate obligation to the Vermont Medicaid Program.

666. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Vermont Medicaid program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

667. Since this program is jointly funded by Vermont and the United States, Mallinckrodt's conduct directly resulted in significant financial loss to the State of Vermont and the United States.

668. By virtue of the false or fraudulent claims, and/or false records or statements, Mallinckrodt made or caused to be made, the State of Vermont suffered damages and therefore is entitled to recover from Mallinckrodt treble damages under the Vermont False Claims Act, in an amount to be proved at trial, plus a civil penalty for each violation and the costs of the investigation and prosecution.

Count CII – Breach of Contract

669. The State of Vermont repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

670. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Vermont was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

671. For the reasons discussed above, from the first quarter of 2013 through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

672. By virtue of this conduct, Vermont is thus entitled to damages and any other relief the Court deems appropriate.

Count CIII – Unjust Enrichment

673. The State of Vermont repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

674. The Vermont Medicaid Program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely reported its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to Vermont. By falsely reporting its Base Date AMP, Mallinckrodt was able to retain profits for Acthar and avoid paying monies owed to Vermont.

675. By retaining monies that were actually owed to Vermont under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of Vermont and to which it was not entitled.

676. By retaining the use and enjoyment of the monies that should have been paid to Vermont pursuant to the Medicaid Rebate Program, Mallinckrodt has been unjustly enriched, and is liable to account for and pay such amounts or the proceeds there from, which are to be determined at trial, to the State of Vermont.

Count CIV – Disgorgement

677. The State of Vermont repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

678. Mallinckrodt failed to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement and retained money that should have been paid to the States, including the State of Vermont.

679. This Court has the equitable power to order defendant Mallinckrodt to disgorge the entire amount of improperly-retained rebate payments that should have been paid to the States.

680. Vermont seeks disgorgement of all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement.

CLAIMS OF THE COMMONWEALTH OF VIRGINIA

Count CV – Reverse False Claims

(Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(7) (2018))

681. The Virginia Attorney General brings this action in the name of the Commonwealth of Virginia for damages resulting from false claims submitted to the Virginia Department of Medical Assistance Services⁹ (“DMAS”), the agency that administers the Virginia Medicaid

⁹ For the purposes of this Complaint, the term “DMAS” includes, and is interchangeable with, the Virginia Medicaid Program and any contractors or managed care organizations engaged by, or working on behalf of, DMAS or the Virginia Medicaid Program.

Program. The Commonwealth of Virginia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

682. The Virginia Fraud Against Taxpayers Act (“VFATA”), Va. Code Ann. § 8.01-216.3(A), provides, in pertinent part, that 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 Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth; shall be liable to the Commonwealth for a civil penalty of not less than \$10,957 and not more than \$21,916, except that these lower and upper limits on liability shall automatically be adjusted to equal the amounts allowed under the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended (28 U.S.C. § 2461 Note, P.L. 101-410), plus three times the amount of damages sustained by the Commonwealth.

VA. CODE ANN. § 8.01-216.3(A) (2018).¹⁰

683. The VFATA defines the terms “knowing” and “knowingly” to 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 require no proof of specific intent to defraud.” VA. CODE ANN. § 8.01-216.3(C) (2018).

684. For each unit of Acthar purchased for a Virginia Medicaid Program recipient, Mallinckrodt has an obligation under the Rebate Statute, 42U.S.C. § 1369r-8, to pay quarterly rebates using Acthar’s 1990 price as its Base Date AMP. Mallinckrodt has improperly avoided and decreased this obligation for every quarter since 2013 by paying a much lower rebate amount, using Acthar’s 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has

¹⁰ The amount of the civil penalty changes over time. For example, the 2011 version of the Code provides for a “civil penalty of not less than \$5,500 and not more than \$11,000.” VA. CODE ANN. § 8.01-216.3(A) (2011).

knowingly avoided and decreased its total Virginia Medicaid rebate obligation by millions of dollars.

685. Since at least April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of CMS's requests for corrective action. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. Mallinckrodt continued to knowingly and improperly avoid and decrease its rebate obligation to the Commonwealth of Virginia from 2013 through the first quarter of 2020, when it corrected the Base Date AMP.

686. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that if it did so, the Virginia Medicaid Program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement for all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

687. The Virginia Medicaid Program is jointly funded by the United States and the Commonwealth of Virginia. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Virginia Medicaid rebates for Acthar, the United States and the Commonwealth of Virginia have incurred significant financial loss.

688. By virtue of Mallinckrodt's conduct, the Commonwealth of Virginia has suffered actual damages and is therefore entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct under the VFATA.

689. In addition to other remedies available under this section, the Court may award the Commonwealth of Virginia reasonable attorney fees and costs of a civil action brought to recover any such penalties or damages. VA. CODE ANN. § 8.01-216.3(A) (2018).

Count CVI – Conversion
(Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(4) (2018))

690. The Virginia Attorney General brings this action in the name of the Commonwealth of Virginia for damages resulting from false claims submitted to DMAS. The Commonwealth of Virginia re-alleges and incorporates by reference all paragraphs of this complaint set about above as if fully set forth herein.

691. The VFATA provides that any person who:

Has 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... shall be liable to the Commonwealth for a civil penalty...plus three times the amount of damages sustained by the Commonwealth.

VA. CODE ANN. § 8.01-216.3(A) (2018).

692. By using a 2013 Base Date AMP instead of the correct 1990 Base Date AMP and thereby underpaying Virginia Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, and/or control of property or money used, or to be used, by the Commonwealth of Virginia. In particular, Mallinckrodt has retained for itself millions of dollars that it should have paid in rebates to the Commonwealth of Virginia. Medicaid rebates collected by the Commonwealth of Virginia offset the overall cost of the Virginia Medicaid Program.

693. Since at least April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the Commonwealth of Virginia, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Virginia Medicaid Program rebate amounts from 2013 through the first quarter of 2020 for Acthar, to the Commonwealth of Virginia.

694. Since at least April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full Virginia Medicaid Program rebate amount due for Acthar for the rebate periods from 2013 through the first quarter of 2020. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. Mallinckrodt knowingly continued to deliver or caused to be delivered less than all of the Virginia Medicaid Program rebates it owed to the Commonwealth of Virginia for Acthar from 2013 through the first quarter of 2020, when it corrected the Base Date AMP.

695. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system for a seven-year period. Mallinckrodt knew that, if it did so, the Virginia Medicaid Program invoices it would receive each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt had an independent obligation under the Rebate Statute to pay the proper rebate amounts, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

696. The Virginia Medicaid Program is jointly funded by the United States and the Commonwealth of Virginia. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Virginia Medicaid rebates for Acthar, the United States and the Commonwealth of Virginia have incurred significant financial loss.

697. By virtue of Mallinckrodt's conduct, the Commonwealth of Virginia has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

698. In addition to other remedies available under this section, the Court may award the Commonwealth of Virginia reasonable attorney fees and costs of a civil action brought to recover any such penalties or damages. VA. CODE ANN. § 8.01-216.3(A) (2018).

Count CVII – Unjust Enrichment

699. The Virginia Attorney General brings this action in the name of the Commonwealth of Virginia for damages resulting from false claims submitted to DMAS. The Commonwealth of Virginia re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

700. Since January 1, 2013, Mallinckrodt would have been required to pay substantially larger rebates to the Commonwealth of Virginia if it had utilized the correct Base Date AMP for Acthar. Instead, by using the incorrect Base Date AMP from 2013 through the end of the first quarter of 2020, Mallinckrodt retained monies that were actually owed to the Commonwealth of Virginia under the MDRP. As such, Mallinckrodt retained money that was the property of the Commonwealth of Virginia and to which it was not entitled.

701. Mallinckrodt has been unjustly enriched by retaining the use and enjoyment of monies that it should have paid to the Commonwealth of Virginia pursuant to the MDRP had it

used the correct Base Date AMP to calculate the amount of Medicaid rebates it owed the Commonwealth of Virginia for Acthar.

702. By virtue of Mallinckrodt's conduct, the Commonwealth of Virginia has suffered actual damages.

703. This Court has the equitable power to order Mallinckrodt to disgorge the entire amount of improperly retained rebate payments that should have been paid to the Commonwealth of Virginia.

704. The Commonwealth of Virginia seeks disgorgement of all unpaid rebates based upon Mallinckrodt's failure to comply with its obligations under the Medicaid Rebate Statute and Rebate Agreement.

Count CVIII – Common Law Fraud

705. The Virginia Attorney General brings this action in the name of the Commonwealth of Virginia for damages resulting from false claims submitted to DMAS. The Commonwealth of Virginia repeats and re-alleges the allegations contained in all of the proceeding paragraphs as if fully set forth herein.

706. Since the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements about Acthar's Base Date AMP to the United States and the Commonwealth of Virginia.

707. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

708. Mallinckrodt intended that Commonwealth of Virginia act or refrain from acting in justifiable reliance on these misrepresentations.

709. The Commonwealth of Virginia did, in fact, rely upon Mallinckrodt's fraudulent misrepresentations. As a result, between 2013 and the first quarter of 2020, the Commonwealth of Virginia received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements regarding its Base Date AMP.

710. As a result of Mallinckrodt's conduct, the Commonwealth of Virginia suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

CLAIMS OF THE STATE OF WASHINGTON

Count CIX – Reverse False Claims **(Washington Medicaid Fraud False Claims Act, Rev. Code Wash. § 74.66.020(1)(g))**

The State of Washington re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

711. For each unit of Acthar the Washington State Medicaid program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013 through the first quarter 2020, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Washington State Medicaid rebate obligation by millions of dollars.

712. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying

amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. While Mallinckrodt has recently took corrective action, it still knowingly and improperly avoided and decreased its rebate obligation to Washington State Medicaid for the period 2013 through first quarter 2020.

713. Mallinckrodt also previously refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that if it had done so, the Washington State Medicaid program invoices it received each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system until recently further facilitated its improper avoidance and decreasing of that obligation.

714. The Washington State Medicaid program is jointly funded by the United States and the State of Washington. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Washington Medicaid rebates for Acthar, the United States and the State of Washington have incurred significant financial losses.

715. By virtue of Mallinckrodt's conduct, the State of Washington has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count CX – Conversion
(Washington Medicaid Fraud False Claims Act, Rev. Code Wash. § 74.66.020(1)(d))

716. The State of Washington re-alleges and incorporates by reference all paragraphs of

this complaint set out above as if fully set forth herein.

717. By using a 2013 Base Date AMP instead of a 1990 Base Date AMP and thereby underpaying Washington Medicaid rebates for Acthar, Mallinckrodt has retained possession, custody, or control of property or money used, or to be used, by the government. In particular, Mallinckrodt has retained for itself tens of millions of dollars that it should have paid in rebates to the Washington State Medicaid Program. Medicaid rebates collected by Washington offset the overall cost of the Washington Medicaid program.

718. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the State of Washington, and also knowingly delivered and caused to be delivered less than all of this money or property, in the form of unpaid Medicaid rebate amounts from 2013 through the first quarter 2020 for Acthar, to the State of Washington.

719. Since no later than April 2016, Mallinckrodt knew that it delivered and caused to be delivered less than the full rebate amount due for Acthar for the rebate periods from 2013 through the first quarter 2020. Mallinckrodt understood that CMS's requested corrective action meant using Acthar's 1990 Base Date AMP going forward and repaying amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS warned it to take. While Mallinckrodt recently took corrective action, it still knowingly and improperly avoided and decreased its rebate obligation to Washington State Medicaid for the period 2013 through first quarter 2020.

720. Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knows that if it had done so, the Washington Medicaid program invoices it receives each quarter would seek payment for much larger rebate amounts and

would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's prior refusal to update the DDR system further facilitates its improper avoidance and decreasing of that obligation.

721. The Washington State Medicaid program is jointly funded by the United States and the State of Washington. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Medicaid rebates for Acthar, the United States and the State of Washington have incurred significant financial losses.

722. By virtue of Mallinckrodt's conduct, the State of Washington has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance of unlawful conduct.

Count CXI – Unjust Enrichment

723. The State of Washington repeats and realleges the allegations contained in all of the preceding paragraphs as if fully set forth herein.

724. The Washington State Medicaid program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely inflated its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to Washington State. By retaining monies that were actually owed to Washington under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of the State of Washington and to which it was not entitled.

725. By retaining the use and enjoyment of the monies that should have been paid to the State of Washington pursuant to the Medicaid Rebate Program, Mallinckrodt has been unjustly

enriched, and is liable to account for and pay such amounts or the proceeds there from, which are to be determined at trial.

CLAIMS OF THE STATE OF WISCONSIN

Count CXII – Reverse False Claims **(Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931(2)(g))**

726. The State of Wisconsin re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

727. For each unit of Acthar the Wisconsin Medicaid Program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Wisconsin Medicaid rebate obligation by tens of millions of dollars.

728. Since no later than 2013, Mallinckrodt has known and intentionally underpaid these lower rebates. Mallinckrodt calculated the amount of rebates it avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid and decrease its rebate obligation to Wisconsin Medicaid.

729. Since no later than 2013, and continuing through the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Wisconsin Medicaid Program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date

AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

730. The Wisconsin Medicaid Program is jointly funded by the United States and the State of Wisconsin. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Wisconsin Medicaid rebates for Acthar, the United States and the State of Wisconsin have incurred significant financial losses.

731. By virtue of Mallinckrodt's conduct, the State of Wisconsin has suffered actual damages and is therefore entitled to treble damages under the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931(2)(g) (repealed July 2015) to be determined at trial, plus forfeitures of not less than \$5,000 and not more than \$10,000 for each violation.

Count CXIII – Reverse False Claims
(Wisconsin Medical Assistance Act, Wis. Stat. § 49.49(4m)(a)(3))

732. The State of Wisconsin re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

733. For each unit of Acthar the Wisconsin Medicaid Program purchases, Mallinckrodt has an obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to pay quarterly rebates using Acthar's 1990 price as its Base Date AMP. For every quarter since 2013, Mallinckrodt has improperly avoided and decreased this obligation by paying a much lower rebate amount, using Acthar's 2013 price as its Base Date AMP instead. In this manner, Mallinckrodt has avoided and decreased its Wisconsin Medicaid rebate obligation by tens of millions of dollars.

734. Since no later than April 2016, Mallinckrodt has known that it paid these lower rebates in defiance of requests for corrective action by CMS. Mallinckrodt understood that CMS's requested corrective action meant using the 1990 Base Date AMP going forward and repaying

amounts previously underpaid. Mallinckrodt also contemporaneously calculated the amount of rebates it had already avoided (from 2013 through April 2016) and the percentage of rebates it would avoid going forward, if it refused to take the corrective action CMS requested and then directed it to take. To date, though Mallinckrodt has corrected its Base Date AMP, it knowingly and improperly continues to avoid and decrease its rebate obligation to Wisconsin Medicaid.

735. Since no later than 2013, and continuing through the first quarter of 2020, Mallinckrodt also refused to report the 1990 Base Date AMP for Acthar in the Medicaid DDR system. Mallinckrodt knew that if it did so, the Wisconsin Medicaid Program invoices it receives each quarter would seek payment for much larger rebate amounts and would also seek reimbursement of all prior underpayments resulting from Mallinckrodt's use of a 2013 Base Date AMP for Acthar. Although Mallinckrodt has an independent obligation under the Rebate Statute to pay the proper rebate amount, Mallinckrodt's refusal to update the DDR system further facilitated its improper avoidance and decreasing of that obligation.

736. The Wisconsin Medicaid Program is jointly funded by the United States and the State of Wisconsin. As a result of Mallinckrodt's knowing and improper failure to pay the correct amount of Wisconsin Medicaid rebates for Acthar, the United States and the State of Wisconsin have incurred significant financial losses.

737. By virtue of Mallinckrodt's conduct, the State of Wisconsin has suffered actual damages and is therefore entitled to treble damages under the Wisconsin False Claims for Medical Assistance Act, to be determined at trial, plus forfeitures of not less than \$100 and not more than \$15,000 for each violation.

738. In addition to other remedies available under this section, the Court may award the State of Wisconsin the reasonable and necessary costs of investigation, an amount reasonably

necessary to remedy the harmful effects of the violation and the reasonable and necessary expenses of prosecution, including attorney fees.

Count CXIV – Common Law Fraud

739. The State of Wisconsin re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

740. From the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt made and/or caused to be made fraudulent statements to the United States and the State of Wisconsin that the Base Date AMP for Acthar was 2013. These statements were fraudulent because the correct Base Date AMP for Acthar is 1990.

741. Mallinckrodt made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

742. Mallinckrodt intended that Wisconsin act or refrain from acting in justifiable reliance on these misrepresentations.

743. Wisconsin did, in fact, rely upon Mallinckrodt's fraudulent misrepresentations. As a result, between 2013 through present, Wisconsin received substantially lower rebate payments for Acthar than it would have been entitled to receive had Mallinckrodt submitted true and accurate statements of its Base Date AMP.

744. As a result of Mallinckrodt's conduct, the State of Wisconsin suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

Count CXV – Breach of Contract

745. The State of Wisconsin re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

746. As discussed above, Mallinckrodt entered into a Rebate Agreement with the United States. The State of Wisconsin was an intended third-party beneficiary of that contract. Under the terms of the agreement, Mallinckrodt had a duty to, *inter alia*, accurately report its Base Date AMP for Acthar.

747. For the reasons discussed above, from the first quarter of 2013 and continuing through the first quarter of 2020, Mallinckrodt breached that agreement by failing to accurately report its Base Date AMP for Acthar.

748. By virtue of this conduct, Wisconsin is thus entitled to damages and any other relief the Court deems appropriate.

Count CXVI – Unjust Enrichment

749. The State of Wisconsin re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

750. The Wisconsin Medicaid Program received substantially lower Medicaid rebates than it would have received had Mallinckrodt truthfully reported its Base Date AMP for Acthar. If Mallinckrodt had not falsely reported its Base Date AMP, Mallinckrodt would have been required to pay substantially larger rebates to Wisconsin. By falsely reporting its Base Date AMP, Mallinckrodt was able to retain profits for Acthar and avoid paying monies owed to Wisconsin.

751. By retaining monies that were actually owed to Wisconsin under the Medicaid Rebate Program, Mallinckrodt retained money that was the property of Wisconsin and to which it was not entitled.

752. By retaining the use and enjoyment of the monies that should have been paid to Wisconsin pursuant to the Medicaid Rebate Program, Mallinckrodt has been unjustly enriched, and is liable to account for and pay such amounts or the proceeds therefrom, which are to be determined at trial, to the State of Wisconsin.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand that judgment be entered in favor of the Plaintiff States against defendant Mallinckrodt on each count of this Complaint and to impose damages and penalties as described above and to the full extent allowed by law and in equity and award all costs and fees as applicable under state law.

DEMAND FOR JURY TRIAL

The Plaintiff States respectfully demand trial by jury in this case.

DATED: _____

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (“NEF”) and paper copies will be sent to those indicated as non-registered participants on July 16, 2020.

/s/ Cedell Ian Garland
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