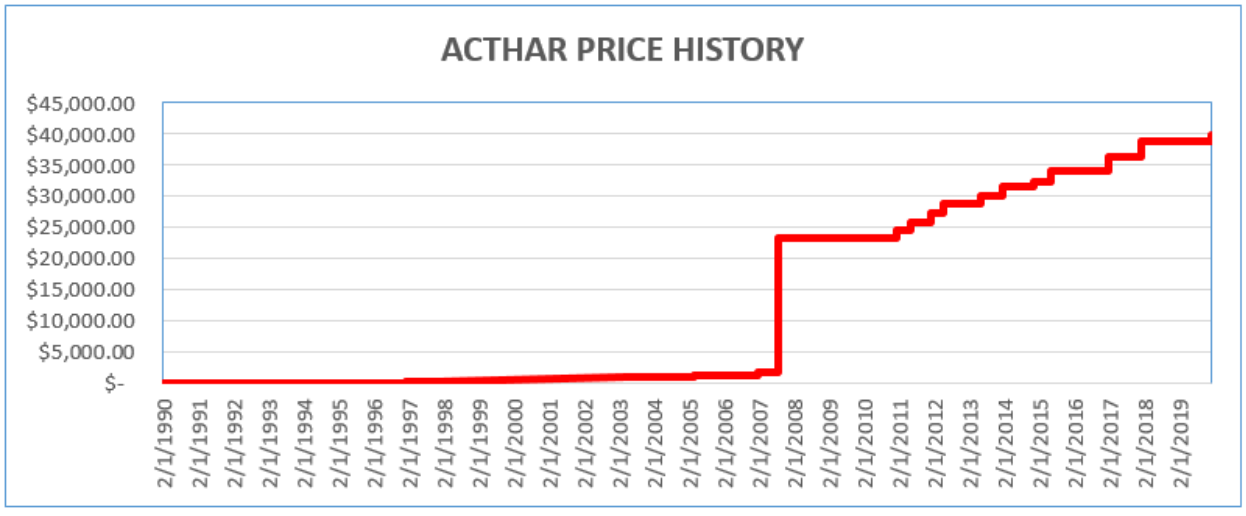
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSSETS

UNITED STATES OF AMERICA, *et al., 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

UNITED STATES' COMPLAINT IN INTERVENTION

The United States brings this action to recover hundreds of millions of dollars in rebates that defendant Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD, Inc. and previously Questcor Pharmaceuticals, Inc.) (collectively "Mallinckrodt") illegally withheld from the Medicaid program for its drug Acthar. Mallinckrodt's substantial rebate obligation largely results from its dramatic price increases for Acthar. Mallinckrodt did not develop Acthar. When its predecessor, Questcor, acquired it in 2001, the drug cost approximately $50 per 5mL vial. Since then, Mallinckrodt has increased Acthar's price to nearly $40,000 per vial:



Under the Medicaid Drug Rebate Program ("MDRP"), when a manufacturer raises the price of a drug faster than the rate of inflation, the manufacturer must pay the Medicaid program a per unit rebate of the difference between the drug's current price and the price the drug would have had 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 first came to market in the 1950s. Because the increases in Acthar's price since 1990 have far outpaced inflation, the inflationary rebate on Acthar now should amount to nearly the entire cost of the drug.

Rather than paying rebates based on the extraordinary increases in Acthar's price since 1990, Mallinckrodt began in 2013 to pay rebates on Acthar as if it had first marketed the drug in 2013. Mallinckrodt purports to have made this change under the guise of an August 2012 letter to Questcor from the Centers for Medicare and Medicaid Services ("CMS"). Earlier in 2012, Questcor had requested that CMS approve a later starting price for calculating Acthar's inflationary rebate. In support of its request, Questcor emphasized that the Food and Drug Administration ("FDA") "approved Acthar under NDA 22-432 for treatment of infantile spasms on October 15, 2010." CMS responded that Questcor could proceed "because Acthar was approved under a new NDA" in 2010. The agency cautioned that its decision was "limited to and based on the facts and information presented to" it.

In fact, however, Questcor's representations to CMS were misleading and the factual premise of CMS's resulting decision was incorrect, as Questcor well knew. When Questcor represented to CMS that the FDA had approved Acthar "under NDA 22-432," it did not disclose that this approval was not for a new, separate NDA or for a new drug. Instead, in 2010, FDA approved an efficacy supplement for infantile spasms to Acthar's preexisting 1952 NDA. When describing it elsewhere, Questcor itself referred to this approval as a "supplemental NDA." After

2010, Acthar remained unchanged from the version that had been on the market for decades. Further, NDA number 22-432 was, as Questcor understood from the FDA, only a "tracking number" that the FDA had created for internal "administrative purposes" and that Questcor had acknowledged "would no longer be used" because the approval for infantile spams would merge into the 1952 "parent NDA."

By 2016, CMS discovered many of the key facts Questcor omitted in its 2012 letter and directed the company (now named Mallinckrodt) to correct all of its underpayments since 2013 and to pay future Medicaid rebates for Acthar based on all of the price increases for the drug since 1990. Mallinckrodt refused. CMS has repeated its direction numerous times since and has made clear that the FDA assignment of an NDA tracking number to Questcor's efficacy supplement for administrative purposes offered no basis for Mallinckrodt to ignore pre-2013 price hikes when paying Medicaid rebates for Acthar. In response to every CMS request for corrective action, Mallinckrodt continued to refuse, even though, as one Mallinckrodt employee noted, the company's regulatory function "agreed with CMS basically." Mallinckrodt's continued defiance has enabled it to avoid paying hundreds of millions of dollars in rebates that should have insulated Medicaid from Acthar's meteoric price rise prior to 2013. Instead, the taxpayers who fund Medicaid have absorbed the brunt of Acthar's ever-increasing cost, in contravention of federal law and Congress's intent in establishing the MDRP.

JURISDICTION, VENUE, PARTIES

1. This action arises under the False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-33. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

2. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

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

4. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services ("HHS"), and, specifically, its operating division, CMS.

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

6. Defendant Mallinckrodt ARD LLC, 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 206, Bedminster, NJ 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and, prior to that, was named Questcor Pharmaceuticals, Inc. ("Questcor").

7. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and effectuated the acquisition of Questcor on August 14, 2014. Questcor survived the merger as a wholly owned indirect subsidiary of Mallinckrodt plc and continued to market Acthar thereafter, until changing its name to Mallinckrodt ARD, Inc. on July 27, 2015. On January 26, 2019, Mallinckrodt ARD, Inc., converted to Mallinckrodt ARD LLC.

8. Mallinckrodt has marketed Acthar throughout the United States at all relevant times for purposes of this complaint in intervention. Mallinckrodt underpays rebates on Acthar to Medicaid programs nationwide, including to MassHealth, the Massachusetts Medicaid program.

LEGAL BACKGROUND

I. THE MEDICAID DRUG REBATE PROGRAM

9. Medicaid is a joint federal-state program that provides health care benefits, including prescription drug coverage, for certain groups, primarily the poor and disabled. 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 the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the federal contribution is at least 50 percent, and, currently, as high as 76.98 percent.

10. In 1990, Congress reviewed the prices that Medicaid was paying for prescription drugs and determined that Medicaid routinely was paying more than other large drug purchasers for prescription drugs, particularly for "single source" or "branded" drugs (*e.g.*, drugs like Acthar). *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Congress thereafter enacted the Medicaid Drug Rebate Statute ("Rebate Statute"), 42 U.S.C. § 1396r-8. The Rebate Statute states that, in order for a drug manufacturer's drugs to be eligible for federal payment under Medicaid, the drug manufacturer must enter into a Rebate Agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(a)(1). The Rebate Statute sets the terms of the Rebate Agreement. The nationwide template Rebate Agreement, or "National Drug Rebate Agreement" ("NDRA") is published in the Federal Register. CMS published the original version in 1991, *see* Medicaid Program, Drug Rebate Agreement, 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991), and an updated version in 2018, *see* Medicaid Program, Announcement of Medicaid Drug Rebate Program National Rebate Agreement, 83 Fed. Reg. 12770, 12784 (Mar. 23, 2018). Questcor signed a Rebate Agreement in 2002 under labeler code

63004. (A copy of that agreement is attached as Exhibit 1.) Mallinckrodt signed a Rebate Agreement in 1991, enrolling under labeler code 00406, and another in 2007, enrolling under an additional labeler code, 23635. (Copies of these agreements are attached as Exhibits 2 and 3.) Mallinckrodt signed updated versions of each agreement in 2018. (Copies of these agreements are attached as Exhibits 4 and 5.)

11. Among other obligations, both the Rebate Statute and Rebate Agreement require manufacturers to pay each state Medicaid program a quarterly rebate per unit of each "dosage form and strength" of a "covered outpatient drug,"[1] purchased by Medicaid during the quarter at issue, 42 U.S.C. § 1396r-8(c), within 30 days of each state reporting to the manufacturer "information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed . . . for which payment was made" by the state Medicaid program that quarter. 42 U.S.C. § 1396r-8(b)(1), (2).

12. The Rebate Statute requires manufacturers to pay a quarterly rebate for each "dosage form and strength" of a covered outpatient drug. *See* 42 U.S.C. 1396r-8(c) ("Determination of amount of rebate"). The statute sets forth different rebate calculation formulas for different categories of "covered outpatient drugs," which the statute defines as either: "single source," "innovator multiple source," or "non-innovator multiple source" drugs. 42 U.S.C. § 1396r-8(k)(7).

13. In general, "single source" drugs (*i.e.*, brand name drugs without FDA-rated therapeutic equivalents) are subject to the highest rebate obligations.

[1] 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).

14. The Rebate Statute defines a "single source" drug as a "covered outpatient drug" "produced or distributed under a new drug application approved by the Food and Drug Administration." 42 U.S.C. § 1396r-8(k)(7)(A)(iv).[2]

15. To insulate Medicaid from drug price increases that outpace inflation, the Rebate Statute requires manufacturers to pay an "additional rebate" for each "dosage form and strength of a single source drug." 42 U.S.C. § 1396r-8(c)(2). If the drug was approved by the FDA and marketed by July 1, 1990, 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). The Rebate Statute sets forth this requirement for an additional rebate 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

[2] Prior to April 18, 2019, the statute defined a "single source" drug as a "covered outpatient drug" "produced or distributed under an *original* new drug application approved by the Food and Drug Administration." 42 U.S.C. § 1396r-8(k)(7)(A)(iv) (2018) (emphasis added).

> 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).

16. For covered outpatient drugs approved by the FDA and first marketed after July 1, 1990, the Rebate Statute applies the same formula but uses the first full quarter after the drug was first marketed 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 sets forth this methodology as follows:

> 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).

17. In general, whether using the 1990 AMP, 42 U.S.C. § 1396r-8(c)(2)(A)(ii)(II) or, for subsequently approved drugs, a later AMP corresponding to the "first full calendar quarter after the day on which the drug was first marketed," 42 U.S.C. § 1396r-8(c)(2)(B), 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.").

18. If a manufacturer increases the price of a "single source drug" drug much faster than the rate of inflation, the "additional rebate" owed for that drug can be substantial. The Rebate Statute provides, however, that the total rebate owed "with respect to each dosage form

and strength of a single source drug" cannot "exceed 100 percent of the [AMP] of the drug." 42 U.S.C. § 1396r-8(c)(2)(D).

19. The Rebate Statute requires manufacturers to make quarterly reports to CMS with certain pricing information, including AMP, for each drug. *See* 42 U.S.C. § 1396r-8(b)(3). Manufacturers report such information through CMS's Drug Data Reporting ("DDR") system and certify its accuracy to CMS. Manufacturers report a drug's Base Date AMP to CMS at the outset of that drug entering the MDRP.

20. Manufacturers are independently responsible for calculating and paying the proper rebates owed for each of their drugs. Nonetheless, as a courtesy, CMS takes the manufacturer-reported information 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."). CMS transmits URAs to the states, which may, along with providing the required notice of total Medicaid utilization of the drug, invoice the manufacturers for a total rebate amount owed based upon these URAs. *See* NDRA at § II(b), 83 Fed. Reg. at 12785 ("CMS may calculate a URA based on a manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing."). CMS's calculation and communication of URAs does not relieve manufacturers of their independent obligations to pay the proper rebate amounts under the Rebate Statute and Rebate Agreement. 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.").

21. The Rebate Agreement further provides that, "[t]o 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.

II. FDA APPROVAL OF NEW DRUG APPLICATIONS

22. The new drug application ("NDA") is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. An NDA refers to "stand-alone" applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act and to section 505(b)(2) applications. 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.3(b).

23. When a manufacturer submits an NDA for approval to market a new drug, the FDA assigns that drug a unique six-digit NDA number. Following approval, the FDA permits manufacturers to make iterative changes to the drug or its labeling through the supplemental new-drug-application ("sNDA") process. *See* 21 C.F.R. §§ 314.70–71. One such change is the addition of a new "indication" – 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. The FDA has explained that, after it approves an NDA, "[a] request for approval of a new indication, or a modification of a previously approved indication, 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.

Specifically, an "efficacy supplement" includes "a supplement to an approved NDA proposing to … [a]dd or modify an indication." 21 C.F.R. § 314.3(b).

24. Each supplement is sequentially numbered (e.g. 001, 002, 003), but the drug retains the same six-digit NDA number. *See* Drugs@FDA Glossary of Terms, "Supplement Number," *available at* https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#S.

25. Prior to July 27, 2009, when a new indication in a supplemental application needed to be reviewed by an FDA division other than the one responsible for the original NDA, the FDA created a "Type 6 NDA," with an associated NDA tracking number. The FDA's classification manual explains that a Type 6 NDA was assigned when a drug product "duplicates a drug product already approved or marketed in the United States by the same applicant, except that it is intended for a new indication or claim." FDA NDA Classification Manual at 5, *available at* https://www.fda.gov/media/94381/download. Because they had only an administrative function, the FDA closed Type 6 NDAs upon approval. These Type 6 tracking NDAs became obsolete after July 27, 2009, with FDA's implementation of the Document Archiving, Reporting and Regulatory Tracking System (DARRTS). *See id.*

26. A manufacturer may assign several different national drug code ("NDC") numbers to a drug approved under a single NDA through the FDA NDC assignment process. The NDC number is typically an eleven-digit code that contains the manufacturer's labeler code, the product code, and the package code. *See* 21 C.F.R. § 207.33. Having multiple NDCs, therefore, does not mean that the drug's composition has changed.

27. The FDA's Orange Book – formally entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (*available at*

https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm) – lists all marketed drug products that the FDA has approved under section 505 of the FDCA. The Orange Book satisfies the FDA's statutory obligation to make publicly available a list of approved drug products with monthly supplements.

III. THE FALSE CLAIMS ACT

28. The FCA 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 Government and knowingly delivers, or causes to be delivered, less than all of that money or property; [or]
>
> **(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 Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> . . .is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

29. For purposes of the FCA, 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. 31 U.S.C. § 3729(b)(1).

30. The FCA 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[.]

31 U.S.C. § 3729(b)(3).

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

FACTUAL BACKGROUND

I. BACKGROUND ON ACTHAR GEL

32. Acthar is an adrenocorticotrophic hormone analogue that is injected either beneath the skin (subcutaneously) or into the muscle (intramuscularly), depending on its use. Acthar's active ingredient is extracted from pig pituitary glands.

33. In 1952, the FDA approved Acthar for marketing in the United States under NDA 008372. Since 1952, NDA 008372 has been supplemented more than two dozen times, and Acthar's labeling now has nineteen indications.

34. Questcor acquired Acthar from another manufacturer in 2001.

II. QUESTCOR'S SUPPLEMENTAL APPLICATION TO APPROVE THE EXISTING ACTHAR DRUG FOR A NEW INDICATION

35. In 2006, Questcor submitted a supplemental application for NDA 008372. Through this sNDA, which the FDA identified as "sNDA 08-372/S-039," Questcor sought to supplement NDA 008372 with an indication for infantile spasms, a seizure disorder that occurs in young children.

36. On August 8, 2008, after the FDA had started processing the supplemental indication application for Acthar, the FDA sent Questcor an e-mail stating that the FDA had "created a separate NDA number for your infantile spasm submission **for administrative**

purposes," and that "[t]he new number is NDA 22-432." (A copy of this e-mail is attached as Exhibit 6.) (Emphasis added.)

37. The FDA also documented the administrative nature of this NDA number in an internal memo dated August 8, 2008. The memo stated that the FDA had created a Type 6 NDA number in this instance so that the supplemental indication application could be reviewed by the proper FDA division with expertise and oversight for infantile spasms. (A copy of this memo is attached as Exhibit 7.)

38. Reflecting that NDA 22432 was an administrative, Type 6 NDA number for Acthar, FDA correspondence with Questcor continued to refer to the pending Acthar application as a "supplemental new drug application," and as a "REVIEW EXTENSION – EFFICACY SUPPLEMENT." (Copies of these letters are attached as Exhibits 8, 9, and 10.) In other words, the FDA made clear that NDA 22432 concerned the same drug the FDA approved in 1952 under NDA 008372.

39. Questcor amended the 2006 supplemental indication application in December 2009 and multiple times in 2010, before the FDA ultimately approved the infantile spasms indication application on October 15, 2010. In conjunction with the approval, the FDA also revised Acthar's label by removing certain other indications the FDA had approved prior to the enactment of modern efficacy and safety review standards.

40. The FDA's 2010 approval letter reflected the temporary, administrative nature of NDA number 022432. Specifically, the FDA's letter directed Questcor to address all future submissions to "the original **NDA 008372** for this drug product, not to this NDA [022432]," with

the exception of the final printed labeling requested by FDA. (A copy of this letter is attached as Exhibit 11.) (Emphasis in original.)

41. Questcor knew that the FDA's action was the approval of its 2006 supplemental application for the existing Acthar drug, not the approval of a new drug. Thus, in the Form 10-Q Questcor filed with the Securities and Exchange Commission on November 2, 2010, the company wrote: "On October 15, 2010, the FDA approved our **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. Likewise, in a press release announcing the FDA approval, Questcor acknowledged that the FDA approval was for a "**supplemental** new drug application (NDA)," not an NDA for a new drug. *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. Further, in a May 3, 2011 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." (A copy of this letter is attached as Exhibit 12.) (Emphases added.) In that letter, Questcor recognized that, "since the tracking NDA number [22432] will no longer be used, we are submitting this Changes Being Effected Labeling Supplement to the **parent NDA 08,372**." (Emphasis added.) Similarly, in March 5, 2011 application for a labeling supplement, Questcor characterized 22432 as a "tracking NDA." (A copy of this application is attached as Exhibit 13.) The FDA approved this supplement, following a 2014 amendment by Questcor/Mallinckrodt, on March 24, 2015. The FDA's approval letter reiterated what the

company had stated in its May 2011 letter to FDA: namely, 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." (A copy of this approval letter is attached as Exhibit 14.)

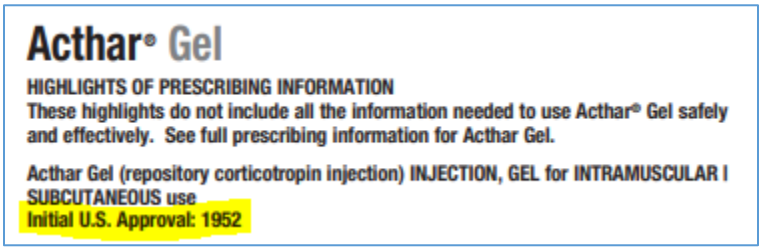
42. Consistent with the FDA's direction not to submit anything further to tracking NDA 022432, which would be closed, Mallinckrodt has regularly supplemented NDA 008372 rather than NDA 0022432, most recently with a proposed revision to the labeling text in July 2018. Mallinckrodt wrote: "Reference is made to [Mallinckrodt] New Drug Application (NDA) 08372 for H.P. Acthar Gel (repository corticotropin injection). The [FDA] approved Acthar in 1952 for multiple indications. The indication for treatment of Infantile Spasms in infants and children under 2 years of age was granted on October 2010." Mallinckrodt further explained that "the H.P. Acthar Gel product trade name," under which it markets the drug, "has been in use since the original product approval in 1952." (A copy of this letter is attached as Exhibit 15.)

43. In the most recent Form 10-K that Mallinckrodt filed with the Securities and Exchange Commission, the company again noted that the FDA's 2010 approval was for a "**supplemental** NDA for use of Acthar Gel in treatment of [infantile spasms]." Mallinckrodt, SEC Form 10-K at 29 (Feb. 26, 2020) (emphasis added), *available at* https://www.sec.gov/ix?doc=/Archives/edgar/data/1567892/000156789220000005/mnk10-k122719.htm.

44. In the Orange Book, the FDA's published list of marketed drug products, the FDA lists Acthar as associated only with 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=0

08372#17292. Moreover, in the Orange Book print version section listing drugs with patents and exclusivity, the FDA lists the orphan exclusivity for Acthar under NDA 008372, not 022432. (A copy of the Orange Book print version page for this listing is included in Exhibit 16.) 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. Because Drugs@FDA, a separate website, includes "tentative approvals and Type 6 approvals," unlike the Orange Book, that website lists NDA number 022432 as a Type 6 submission. *See* Drugs@FDA Frequently Asked Questions, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page#daf_vs_ob. Even Drugs@FDA only lists the 2010 approval associated with NDA number 22432 under the company "Questcor Pharma;" it lists all subsequent activity for Acthar under NDA 08372 and the company "Mallinckrodt ARD." *Compare* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022432 *with* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=008372.

45. Consistent with the 2010 approval being for an sNDA for infantile spasms, and Acthar being exactly the same drug it was before the 2010 approval, Mallinckrodt's FDA-approved label for Acthar still says that the drug was approved in 1952:



Acthar® Gel

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Acthar® Gel safely and effectively. See full prescribing information for Acthar Gel.

Acthar Gel (repository corticotropin injection) INJECTION, GEL for INTRAMUSCULAR I SUBCUTANEOUS use

Initial U.S. Approval: 1952

The full Acthar label is available on the Mallinckrodt website at https://www.acthar.com/pdf/Acthar-PI.pdf.

46. Both before and after the FDA approved adding the infantile spasms indication to Acthar's label in 2010, Questcor and Mallinckrodt produced, distributed, and marketed Acthar under NDA 008372, not under tracking NDA number 022432 or any other supplemental application.

III. IN SEARCH OF A WAY TO AVOID PAYING REBATES RESULTING FROM THE PRICE HIKES IT HAD TAKEN ON ACTHAR, QUESTCOR SUBMITTED MISLEADING INFORMATION ABOUT ACTHAR'S 2010 APPROVAL TO CMS.

47. Because Questcor had increased the price of Acthar much faster than the rate of inflation during the 2000s, the inflationary rebate it owed for Acthar rose to the maximum total rebate amount, or 100% of Acthar's AMP, in any given quarter. Until 2013, Questcor paid this amount, having used Acthar's 1990 Base Date AMP to calculate the inflationary rebates.

48. By 2011, Questcor was looking for a way out of the situation it had created. Rather than lower Acthar's price, which could have reduced the rebates owed, Questcor planned to petition CMS to use a later Base Date AMP, which would mean that Questcor would not have to pay inflationary rebates reflecting the price increases Questcor had taken on Acthar since acquiring the drug in 2001.

49. In March 2012, Questcor met with representatives of CMS's Division of Pharmacy to make this request. In its presentation, Questcor noted that Acthar generated 99.8% of the company's revenues but asserted that the company was losing money on sales to Medicaid beneficiaries because the rebate was "at 100%+ of Medicaid revenue." The company posited two "ways to fix this problem": (1) either CMS could agree to a "New Baseline AMP based on [the 2010 infantile spasms] approval and significant label revision," or (2) accept Questcor's

"Termination of MDRP Participation," after which, Questcor asserted, Medicaid still would be required to cover Acthar for some uses but with "no rebates due." (A copy of Questcor's presentation is attached as Exhibit 17.)

50. In May 2012, Questcor followed up with a formal letter to CMS. (A copy of this letter is attached as Exhibit 18.) The letter repeated Questcor's threat to leave the MDRP if CMS did not permit the company to set a new Base Date AMP for Acthar. Questcor argued that "solutions" exist that "would enable [Questcor] to remain" if CMS agreed to allow Questcor to reset Acthar's Base AMP under either of two rationales: 1) by applying a proposed rule concerning AMP calculation methodologies to allow a reset of the Base Date AMP; or 2) by seeking a new NDC number for Acthar going forward and assigning a new Base Date AMP to all sales under that NDC. In arguing why either rationale was appropriate, Questcor stated that Acthar had been approved in 2010 under a new NDA. Questcor wrote 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." Instead of characterizing the 2010 approval as an efficacy supplement, as both the FDA and Questcor had characterized it in prior communications, Questcor merely included a small font footnote in its letter, stating: "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 spasms is reflected as part of the product's original NDA, No. 08-372. That has not yet occurred."

51. Questcor was not optimistic that CMS would agree to its request. 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." (A copy of this e-mail is attached as Exhibit 19.)

52. Neither Questcor's May 2012 letter nor its March 2012 presentation disclosed certain key facts that the company already knew about the 2010 approval. Questcor did not disclose that it knew the FDA had approved the infantile spasms indication as an efficacy supplement, which Questcor had submitted as an sNDA to Acthar's preexisting 1952 NDA, rather than as a new NDA reflecting a change in the drug. Similarly, Questcor never disclosed to CMS that it knew that NDA number 22-432 was a tracking number assigned for administrative purposes and "will no longer be used." 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 FDA to merge the infantile spasms approval into the label for the 1952 "parent NDA."

53. Based upon Questcor's misleading statements that described the 2010 approval as a separate NDA but omitted these facts, CMS responded in a letter dated August 6, 2012, that "Acthar Gel is eligible for a new base date AMP" because "the recently approved Acthar Gel was approved under a different [NDA] from the original product." (A copy of CMS's letter is attached as Exhibit 20.) CMS sent a follow-up letter on September 19, 2012, correcting a clerical error in the August letter and stating again that, "because Acthar was approved under a new NDA, Questcor may set a new [Base Date AMP]." (A copy of CMS's letter is attached as Exhibit 21.) Both letters made clear that CMS's decision "is limited to and based upon the facts

and information presented to [CMS] and has no applicability to a different set of facts even if such facts appear similar in nature or in scope."

54. Rather than seeking to clarify the agency's misunderstanding or remedy the omissions in its prior communications with the agency, Questcor proceeded to operationalize its plan to pay lower Medicaid rebates on Acthar. In January 2013, Questcor reported a new NDC for Acthar in CMS's DDR system. Despite this new NDC, Acthar itself (*i.e.* the drug) remained unchanged from what had been on the market for decades, and for which Questcor paid rebates using the 1990 Base Date AMP. Nevertheless, Questcor began paying rebates on Acthar with the new NDC as if it had first marketed the drug in 2013 (at a price hundreds of times higher than the drug's price in the third quarter of 1990).

55. As Don Bailey, Questcor's CEO at the time, remarked to Steve Cartt, then Questcor's Chief Commercial Officer, in an e-mail dated August 22, 2012, the reduction in Acthar rebates would "leave[] 76.9% . . . as the pickup in net sales from the new NDC. That calculates out to over $60M [per year]. . . ." Bailey added that, "[s]ince there are no offsetting costs except bonuses, most of this falls to the op income bottom line." In response, Cartt wrote: "Wow, that is stunning." (A copy of this e-mail exchange is attached as Exhibit 22.)

56. After Questcor became part of Mallinckrodt in August 2014, it continued to pay MDRP rebates for Acthar based on the 2013 Base Date AMP.

MALLINCKRODT'S CONTINUED AVOIDANCE OF ITS OBLIGATION TO PAY MEDICAID REBATES ON ACTHAR BASED ON ITS 1990 BASE DATE AMP

I. IN 2016, CMS INSTRUCTED MALLINCKRODT TO CORRECT ACTHAR'S BASE DATE AMP.

57. In a letter dated April 13, 2016, CMS told Mallinckrodt that the 2013 Base Date AMP for Acthar was wrong. (A copy of CMS's letter is attached as Exhibit 23.) The agency

explained that the Acthar with the new NDC was the same drug, marketed under the same 1952 NDA, as the drug with the prior NDC. Specifically, CMS wrote:

> It has recently come to our attention that even though H.P. Acthar Gel is shown to be approved under NDA 022432 on Drugs@FDA, NDC 63004-8710-01 [the new Acthar NDC] is listed as approved under NDA 008372 on FDA Online Label Repository . . . . **As a result of this discrepancy, we have reviewed the approval status of H.P. Acthar Gel and it is our understanding that H.P. Acthar Gel is marketed under NDA 008372 not NDA 022432.** In the [October 15, 2010, FDA Approval Letter], the approval letter shows that although the NDA for the use of H.P. Acthar Gel for infantile spasms was initially assigned number 022432, that any future submissions "should be addressed to the original NDA 008372 for this drug product, not to this NDA [022432]."
>
> When reviewing the reporting of [the new Acthar NDC] to the Medicaid Drug Rebate (MDR) program in the Drug Data Reporting for Medicaid (DDR) system, **we noticed that this NDC has NDA 022432 reported as its FDA application number, which is incorrect pursuant to the FDA approval letter indicated above and the listing information provided by the manufacturer to the FDA Online Label Repository.** Therefore, we are requesting the manufacturer to review and correct the reporting of its product data in DDR to ensure that accurate information is reported to the MDR program.
>
> Additionally, as provided in [CMS-issued Medicaid Guidance entitled "Manufacturer Release No. 90"], **the baseline data of an NDC for a single source drug . . . must follow the NDA. Therefore, the baseline data for [the new Acthar NDC] need to follow the baseline data of the original NDC 63004-7731-01, which includes revision to the base AMP. . . .**

CMS concluded its letter by directing Mallinckrodt to make the "necessary correction."

58. CMS addressed its letter to Kay Forshee, Mallinckrodt's Senior Manager for Government Reporting. At the time, Forshee was responsible for overseeing Mallinckrodt's Medicaid drug price reporting.

59. Mallinckrodt immediately understood that changing Acthar's Base Date AMP back to 1990 would result in Mallinckrodt again owing much higher rebates for Acthar. On April 19, 2016, Melissa ("Misi") Daley, an analyst in Mallinckrodt's government reporting group, sent Forshee a spreadsheet showing that complying with CMS's directive would result in

a 223% increase in the rebate Mallinckrodt owed on Acthar for the first quarter of 2016. In her cover e-mail, Daley wrote: "I thought you could perhaps share [this analysis] with Jamie [Landolt, Mallinckrodt's Director of Internal Controls] and Kathy [Schaefer, Mallinckrodt's Controller] to give them an idea of the possible impact." (A copy of Daley's email, with a redacted version of her analysis, is attached as Exhibit 24.)

II. MALLINCKRODT KNEW CMS WAS RIGHT ABOUT ACTHAR, BUT REFUSED TO TAKE CORRECTIVE ACTION.

60. Two days later, on April 21, 2016, Daley forwarded Forshee an e-mail chain reflecting that Mallinckrodt's regulatory department agreed with CMS regarding Acthar's approval status. (A copy of this e-mail chain is attached as Exhibit 25.) Patty Taylor, a manager in Mallinckrodt's Finance group, had initiated the e-mail chain by asking Kevin Healy, a senior director in Mallinckrodt's Regulatory Affairs department, "to confirm the correct FDA Appl #s for Acthar." Taylor copied Daley on this e-mail. Healy responded to Taylor and Daley 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." Taylor then followed up:

> So does this mean the top one will eventually go away, and the bottom one will be the final NDC and the FDA Approval date will be 04/29/1952?
>
> ~~NDC 63004773101 H.P. ACTHAR GEL 5ML MDV --- Appl # 022432 Approval Date 10/15/2010 (Questcor)~~
>
> NDC 63004871001 ACTHAR GEL 5ML INJECTION --- Appl # 008372 Approval Date 04/29/1952 (Mallinckrodt)
>
> Thanks for your help on this.
>
> Patty Taylor | Sr. Project Manager
> **Mallinckrodt Pharmaceuticals**

In his reply, Healy confirmed that Taylor's understanding was "[c]orrect." When Daley forwarded this exchange to Forshee, she wrote: "You may already know this, but fyi…."

61. When asked about this exchange in sworn testimony, Daley testified that "Regulatory agreed with CMS basically."

62. Forshee also understood this. In her sworn testimony, Forshee testified as follows:

> Yes. Yes. If -- if the regulatory department said the new NDA application is going to go away and be rolled into the old one, then that is kind of inconsistent with what we were communicating to CMS saying, oh, we do have a NDA, and we need a new NDC number, you know. [D]efinitely inconsistency in how Mallinckrodt was treating the NDA and the base AMPs.

Mallinckrodt, however, did not abide by the conclusion of its Regulatory Affairs department.

63. On May 10, 2016, rather than making the necessary correction to the reporting of Acthar's Base Date AMP, Mallinckrodt responded to CMS by merely attaching Questcor's 2012 letter to CMS and CMS's August 2012 response. In the cover e-mail attaching these documents, 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." (A copy of this e-mail, along with subsequent responses, is attached as Exhibit 26.) The e-mail came from Forshee's e-mail address, but others at Mallinckrodt directed her to send it.

64. On June 2, 2016, in replying to Mallinckrodt's May 10, 2016, e-mail, CMS made clear that the 2012 correspondence with Questcor did not provide a basis to report a 2013 Base Date AMP for Acthar, because the Acthar with the new NDC was on the market pursuant to the same NDA Questcor and its predecessors had used to market Acthar with the prior NDC. CMS wrote:

> 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.**

(Emphasis added.)

65. At this point, Forshee understood CMS to be withdrawing any approval it had granted Questcor to reset Acthar's Base Date AMP. She testified that, "[m]y view was CMS saw this as the same product, and they . . . were requesting that we change the baseline AMP to the original baseline AMP."

66. Rather than work to implement CMS's directive, Mallinckrodt instead worked to determine exactly how much money was at stake, and then decided to keep rebuffing the agency.

67. On or about June 3, 2016, Forshee, Landolt, Schaefer, Karen Lasker, Mallinckrodt's Vice President of Commercial Operations, and a Mallinckrodt attorney met to discuss the "CMS Notification – Acthar Baseline AMP." (A copy of the notice for this meeting is attached as Exhibit 27.)

68. Less than two weeks later, on June 16, 2016, Forshee sent Landolt and others a detailed spreadsheet showing that, as of that time, Mallinckrodt would owe $258 million in retroactive Medicaid rebates if it followed CMS's direction and reset Acthar's Base Date AMP back to 1990. (A redacted copy of Forshee's analysis is attached as Exhibit 28.) Forshee testified that she also shared this analysis with Schaefer, and that, "[i]f I recall, everyone's reaction was it was significantly material, the dollar amount."

69. Rather than take corrective action to address its underpayments then, Mallinckrodt dug in further on a position that it knew the company's own regulatory department

did not support. Attempting to avoid a reversion of Acthar's Base Date AMP that would take away the financial windfall the company had enjoyed over the past several years, Mallinckrodt continued to press the notion that there were two different Acthars, marketed pursuant to different NDAs. On July 6, 2016, in an e-mail to CMS from Forshee's account, Mallinckrodt wrote:

> In the April 13, 2016 letter, CMS also stated that it believed that it was potentially incorrect to have listed the product as "ha[ving] NDA 022432 as its FDA application number." We have gone back and confirmed that this was, in fact, the correct FDA assigned application number for the approval of the product that was discussed in the CMS letter of August 6, 2012 and that CMS cited in determining that "[w]e have reviewed your request and agree that Acthar Gel is eligible for a new based date AMP."

The e-mail added that Mallinckrodt would continue to review CMS's correspondence and "will offer additional thoughts . . . at a later date when we have completed our work."

70. On July 29, 2016, Mallinckrodt wrote to CMS again via Forshee's account and advised that the company had "clarified the preexisting FDA Online Label Repository listing to list NDA 022432, consistent with CMS' letter and analysis dated August 6, 2012."

71. In her testimony, Forshee acknowledged the inconsistency between the company's internal view and what it communicated to CMS:

> [R]egulatory is, you know, saying that, no, there's going to be one approval application number, and then finance is saying, well, you know, there's multiple application numbers and multiple approvals, therefore, we should have a new NDC and new baseline AMP.

72. At this time, Mallinckrodt took no steps to correct Acthar's Base Date AMP in the DDR going forward, or to repay the $258 million in Medicaid rebate underpayments that it knew it had accrued. Instead, Mallinckrodt continued to play for time, not communicating with the agency at all on this issue until CMS warned the company again in 2017.

III. CMS WARNED MALLINCKRODT AGAIN IN 2017.

73. On March 20, 2017, with Mallinckrodt still having taken no action to comply with the agency's April 2016 directive to reset Acthar's Base Date AMP back to 1990, CMS sent Mallinckrodt another e-mail reiterating that the 2010 NDA tracking number did not provide any basis to use a 2013 Base Date AMP for Acthar. Specifically, CMS wrote:

> 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.**

(Emphasis added.)

74. Mallinckrodt again refused to take corrective action. Instead, on April 14, 2017, again via Forshee's e-mail account, it responded that it believed the "agency's conclusion was correct in 2012 and remains correct now" because "NDA 022432 represented a very significant set of events," including adding the infantile spasms indication and removing other indications from the label. Mallinckrodt further disputed the relevance of the FDA's treatment of NDA 022432 as a "type-6 NDA" because "[t]he plain language of the Medicaid drug rebate statute speaks directly to the importance of an approval of an NDA; it is irrelevant under the statute

whether an NDA was a 'type 6.'" Mallinckrodt concluded by again stating that it would "continue to review your email" and "may have some additional thoughts to share with you as part of this ongoing dialogue."

75. Although Mallinckrodt's April 2017 e-mail to CMS suggested that the company might follow up with "additional thoughts," it did not. Again, Mallinckrodt chose to wait and refused to implement any corrective action, knowing full well that it continued to underpay Acthar Medicaid rebates and that its $258 million underpayment as of the first quarter of 2016 had continued to grow.

76. Meanwhile, Mallinckrodt well understood that it was acting contrary to the clear warnings of the agency.

77. For example, in a March 2018 slide deck that Lynn Buhl, Mallinckrodt's interim Manager of Government Reporting, prepared for Schaefer to present to the Mallinckrodt board's audit committee, Buhl wrote that, although Questcor initially had received approval from CMS to change Acthar's Base Date AMP, "CMS later retracted its approval and said Acthar had to revert to the Base AMP established in 1990." (A copy of this slide deck is attached as Exhibit 29.) The presentation noted that complying with the CMS directive would create "liability [that] would be retroactive to 2010 through current, and would be in the hundreds of millions of dollars." The same language appeared in several iterations of similar company presentations throughout the remainder of 2018.

IV. CMS WARNED MALLINCKRODT AGAIN IN 2018.

78. On November 6, 2018, with Mallinckrodt continuing to defy the agency's warnings, CMS sent the company a letter demanding that the company change Acthar's Base Date AMP. (A copy of CMS's letter is attached as Exhibit 30.) The letter warned Mallinckrodt that, if it did not comply within 30 days, the agency would lock the company out of the DDR system:

> **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.

(Emphasis added.) The letter further advised that Mallinckrodt was responsible for re-paying the state Medicaid programs the amounts the company previously had underpaid on Acthar rebates: "Mallinckrodt will be responsible for adjusting previous payments to the states using the Prior Quarter Adjustment Statement. . . [and] such changes would be applicable for every quarter for which the base date AMP should have been established based on a market date of 9/30/1990 and not 1/7/2013."

79. Even after receiving CMS's November 2018 letter, Mallinckrodt took no corrective action and continued to avoid its obligation to pay Medicaid the proper rebate amounts for Acthar. In a letter to CMS dated November 12, 2018, Mallinckrodt recounted the company's prior arguments and concluded by requesting "additional time to engage with the Agency on this important issue." (A copy of this letter is attached as Exhibit 31.)

80. In the meantime, on January 18, 2019, the Department of Justice, having received the instant *qui tam* action, sent Mallinckrodt a Civil Investigative Demand for documents concerning Acthar's Base Date AMP.

V. CMS WARNED MALLINCKRODT AGAIN IN 2019.

81. CMS ultimately agreed to an in-person meeting with Mallinckrodt, but that did not take place until March 7, 2019, after the company requested a postponement of the originally-scheduled date.

82. Shortly after the meeting, on March 11, 2019, Mallinckrodt's attorney sent CMS an e-mail advising that the company intended to seek a further meeting with senior CMS officials and requesting that the agency "hold off on any enforcement action with respect to this matter until we have had an opportunity to present our concerns to the Deputy Administrator and to [the HHS Office of General Counsel]." (A copy of this e-mail is attached as Exhibit 32.)

83. The next day, on March 12, 2019, CMS sent Mallinckrodt a letter reiterating that Acthar's Base Date AMP must be the price of the drug in 1990, that the NDA tracking number FDA used for the 2010 supplemental approval did not provide a basis to change the Base Date AMP, and that Mallinckrodt had been underpaying Medicaid rebates on Acthar:

> **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.**

(A copy of this letter is attached as Exhibit 33.) (Emphasis added.)

84. Mallinckrodt still took no corrective action. Instead, it contacted the general counsel of HHS to seek another meeting. On March 27, 2019, the HHS general counsel responded to Mallinckrodt that "the April 13, 2016 letter from CMS to Mallinckrodt constituted CMS' final decision on the relevant issue." Under these circumstances, the general counsel wrote, "any meeting with me would not and could not be productive."

85. On April 12, 2019, Mallinckrodt's general counsel wrote to CMS offering to change Acthar's Base Date AMP back to 1990 on a prospective basis only. As consideration for this offer, Mallinckrodt sought an acknowledgment from CMS that "Mallinckrodt's use of Acthar's post-2012 base date AMP was appropriate." CMS declined this proposal.

86. 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 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.**

(A copy of this letter is attached as Exhibit 34.) (Emphasis added.)

87. To date, Mallinckrodt has not corrected its reporting of Acthar's Base Date AMP, and the company continues to pay Medicaid rebates on Acthar without any consideration for the extraordinary increases in the drug's price prior to 2013.

88. On May 20, 2019, instead of paying the rebates it 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 own regulatory department agreed with CMS in 2016.

VI. MALLINCKRODT'S FRAUD SCHEME HAS CAUSED DAMAGE TO THE GOVERNMENT EVERY QUARTER SINCE JANUARY 1, 2013.

89. Mallinckrodt's conduct has caused significant financial harm to the government.

90. For each quarter since January 1, 2013, Mallinckrodt has received Acthar utilization data from the states and paid Medicaid rebates to them, but has paid an artificially low "additional rebate" calculated using a 2013 Base Date AMP rather than a 1990 Base Date AMP for Acthar.

91. Due to the significant price increases on Acthar since 1990, the statute required Mallinckrodt to pay Medicaid rebates based upon a URA equaling 100 percent of Acthar's AMP every quarter. Instead, and because Mallinckrodt paid rebates based upon a 2013 Base Date AMP (which ignores all price increases prior to 2013), Mallinckrodt paid rebates based upon a much lower URA.

92. Accordingly, for every unit of Acthar reimbursed by Medicaid, Mallinckrodt significantly underpaid its rebate obligation to Medicaid for that unit. Because Acthar's price is

so high, and because Medicaid has reimbursed many units of Acthar, Mallinckrodt has avoided hundreds of millions of dollars in rebates in this manner.

93. Mallinckrodt's failure to pay the correct rebate amount caused the states to incur greater costs to operate their Medicaid programs. Because the federal government funds 50 or more percent of the costs incurred by each state's Medicaid program, Mallinckrodt's conduct has harmed the federal government. In particular, by failing to pay rebates that would lower state Medicaid programs' net costs for Acthar, Mallinckrodt also caused the federal government to pay more for the drug, by paying an FMAP percentage of inflated Medicaid costs for the drug.

COUNT I
(False Claims Act: Reverse False Claims)
(31 U.S.C. § 3729(a)(1)(G))

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

95. 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 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 total Medicaid rebate obligation by hundreds of millions of dollars.

96. 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, Mallinckrodt has taken no such corrective action and knowingly and improperly continues to avoid and decrease its rebate obligation to Medicaid.

97. 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 state Medicaid program invoices it receives 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 amount, Mallinckrodt's refusal to update the DDR system further facilitates its improper avoidance and decreasing of that obligation.

98. The state Medicaid programs are jointly funded by the United States and the states. 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 states have incurred significant financial losses.

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

COUNT II
(False Claims Act: Conversion)
(31 U.S.C. § 3729(a)(1)(D)

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

101. 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 property or money used, or to be used, by the government. In particular, Mallinckrodt has retained for itself hundreds of millions of dollars that it should have paid in rebates to Medicaid. Medicaid rebates offset the overall costs of state Medicaid programs. The federal government funds at least 50 percent of each state program's overall cost pursuant to the applicable FMAP percentage.

102. Since no later than April 2016, Mallinckrodt has knowingly possessed such money used, or to be used, by the government, 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 government.

103. 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.

104. 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 state Medicaid program invoices it receives 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 refusal to update the DDR system further causes the company to deliver less than the proper rebate amounts to Medicaid.

COUNT III
(Unjust Enrichment)

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

106. 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 states, and the United States consequently would have made smaller payments to the states. By retaining monies that were actually owed to the states under the MDRP, Mallinckrodt retained money that was the property of the Medicaid programs and to which it was not entitled.

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

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

I. On Count I under the False Claims Act against Mallinckrodt, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.

II. On Count II under the False Claims Act against Mallinckrodt, for the amount of the United States' damages to be established at trial, trebled as

required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.

III. On Count III under the a common law theory of unjust enrichment against Mallinckrodt, for the amount of the United States' damages to be established at trial, and all such further relief as the Court deems just and proper.

IV. All other and further relief as the Court may deem just and proper.

The United States hereby demands a jury trial on all claims alleged herein.

Dated: March 3, 2020

Respectfully submitted,

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