IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MALLINCKRODT ARD LLC, (f/k/a MALLINCKRODT ARD INC.) 1425 U.S. Route 206 Bedminster, NJ 07921, *Plaintiff*, v. SEEMA VERMA, in her official capacity as ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES, 7500 Security Boulevard, Baltimore, MD 21244, and ALEX M. AZAR II, in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington, D.C. 20201, *Defendants*.	)	Civil Action No. _____

VERIFIED COMPLAINT
SEEKING PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

Plaintiff Mallinckrodt ARD LLC (f/k/a Mallinckrodt ARD Inc.) brings this Complaint against Defendants Seema Verma, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services (CMS), and Alex M. Azar II, in his official capacity as Secretary of the Department of Health and Human Services (HHS), and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action to hold unlawful and set aside a recent decision by CMS regarding the base date average manufacturer price (AMP) under the Medicaid Drug Rebate Program for Mallinckrodt's Acthar Gel® (repository corticotropin) injection. A drug's "base date AMP" is used to calculate the Medicaid rebate amount payable by the drug's manufacturer to state Medicaid agencies when the drug is prescribed to Medicaid beneficiaries. And because the base date AMP is generally used to calculate Medicaid rebates for the entire life of the relevant drug product, it is critically important to get the base date AMP right.

2. In 2010, FDA approved Acthar[1] for use in treating infantile spasms (IS), and awarded it seven years' orphan drug exclusivity for that indication. Acthar is a distinct "single source drug" eligible for its own base date AMP, for several reasons.

3. First, Acthar falls squarely within the statutory definition of a "single source drug," which focuses on whether the drug product is "produced or distributed" under a distinct new drug application (NDA) approved by the Food and Drug Administration (FDA). *See* 42 U.S.C. § 1396r-8(k)(7)(iv). Acthar is produced or distributed under a distinct NDA.

4. Acthar also meets the definition of "single source drug" contained in CMS's own Medicaid drug rebate regulations.

5. And, in August and September 2012, CMS expressly *told* the then-sponsor of the drug, Questcor Pharmaceuticals—twice—that Acthar is a distinct single source drug eligible for its own base date AMP.

[1] There are two Acthars discussed in this complaint: One approved in 2010, and one in 1952. More detail on each will come later. For simplicity's sake, we will refer to the 2010 Acthar as "Acthar" and the 1952 Acthar as "H.P. Acthar Gel."

6. In reliance upon the agency's confirmation, Questcor began reporting the new base date AMP for Acthar in 2013. Mallinckrodt continued to report that base date AMP when it acquired Questcor two years later.

7. CMS has notified Mallinckrodt that it now believes that Acthar was *not* eligible for the previously granted new base date AMP. Since that time, Mallinckrodt has explained to CMS—repeatedly, in emails, letters, and discussions with the agency—that its reversal of position is unlawful. In response, CMS has provided a series of evolving factual and legal arguments in defense of its newfound position.

8. On Friday, May 10, 2019, CMS notified Mallinckrodt that unless it reverts to the old base date AMP within fourteen days—by **May 24, 2019**—CMS will identify Mallinckrodt as being "out of compliance" with its Medicaid Drug Rebate Program reporting requirements. An "out of compliance" finding has automatic repercussions: Mallinckrodt will immediately be barred from submitting pricing data for Acthar to Medicaid, and 90 days after its next reporting deadline, Mallinckrodt will automatically be suspended from the Medicaid Drug Rebate Program. CMS also threatened to refer Mallinckrodt to the Department of Justice and/or U.S. Department of Health and Human Services-Office of Inspector General for further review and investigation.

9. CMS's determination that Acthar is not a distinct single source drug entitled to its own base date AMP conflicts with the plain language of the Medicaid drug rebate statute. It violates CMS's binding regulations. And it deviates from CMS's own long-standing policies—including those articulated (twice) to Questcor in 2012—without adequate explanation or notice. In short, CMS's decision violates both the Administrative Procedure Act (APA) and basic

notions of fair notice, due process, and the prohibition on retroactive rulemaking. It should be overturned.

PARTIES

10. Plaintiff Mallinckrodt is an innovation-driven pharmaceutical company focused on improving outcomes for patients with severe and critical conditions. Mallinckrodt markets and sells Acthar. Mallinckrodt ARD LLC is a California limited liability company with its principal place of business at 1425 U.S. Route 206, Bedminster, NJ 07921.

11. Defendant Seema Verma is the Administrator of CMS, an operating component within HHS. The Administrator maintains an office at 7500 Security Boulevard, Baltimore, Maryland 21244. The Administrator is sued in her official capacity only.

12. Defendant Alex M. Azar II is the Secretary of HHS. Defendant Azar maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201, and is sued in his official capacity only.

JURISDICTION AND VENUE

13. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 28 U.S.C. § 1361, in that this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, in that there exists an actual justiciable controversy as to which Plaintiff requires a declaration of its rights by this Court and injunctive relief to prohibit Defendants from violating laws and regulations.

14. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (e) because this is a civil action in which Defendants are officers of the United States acting in their official

capacities and one of the Defendants maintains his office and conducts business in this judicial district. Moreover, a substantial part of the events giving rise to the claims occurred within this judicial district.

FACTUAL BACKGROUND

The Medicaid Drug Rebate Program

15. Congress established the Medicaid Drug Rebate Program in 1990. *See* 42 U.S.C. § 1396r–8. In a nutshell: in order to ensure that its drug products remain eligible for federal payment under Medicaid, a manufacturer must provide rebates to state Medicaid agencies based on each state's Medicaid beneficiaries' utilization of its covered outpatient drugs during each calendar quarter. *Id.* § 1396r-8(b), (c). Those rebates are shared with the federal government.

16. The unit rebate amount (URA) for a single source drug consists of two components: the basic rebate and the additional rebate. *Id.* § 1396r-8(c). The *basic rebate* is the greater of (i) the difference between the drug's AMP and its best price, as defined by the statute and CMS regulations, or (ii) a statutorily specified minimum rebate percentage of the drug's AMP. *Id.* § 1396r-8(c)(1)(A)(ii). The *additional rebate* is the amount, if any, by which the drug's AMP for the relevant quarter exceeds the "base date AMP," a baseline measure related to the drug's price during a statutorily specified window of time,[2] as adjusted by an inflation factor. *Id.* § 1396r-8(c)(2)(A)(ii). The additional rebate thus requires drug manufacturers to pay greater rebate amounts where price increases outpace the rate of inflation.

17. So, for example, if (1) a drug's base date AMP was $100, (2) that base date AMP, when adjusted for inflation, is $110, and (3) the drug's AMP for the reporting quarter is $120,

[2] For a covered outpatient drug approved on or before October 1, 1990, base date AMP is based on sales in the third quarter of 1990. 42 U.S.C. § 1396r-8(c)(2)(A)(ii)(II). For a covered outpatient drug approved after October 1, 1990, base date AMP is based on the first full calendar quarter of sales. *Id.* § 1396r-8(c)(2)(B).

the drug's price increase has outpaced the rate of inflation, and the additional rebate amount is $120 - $110 = $10 (the difference between the drug's AMP for the relevant quarter and the base date AMP adjusted for inflation). The unit rebate amount is therefore increased by $10, because the additional rebate is added to the basic rebate.

18. The statute requires drug manufacturers to calculate a distinct AMP and URA—and thus a distinct base date AMP—for "each dosage form and strength of a single source drug." 42 U.S.C. § 1396r-8(c)(1)(A). In other words, a drug manufacturer must calculate a new base date AMP if either (a) the product in question is a *different single source drug*; or (b) the product is a *different dosage form or strength* of an existing single source drug.[3]

19. Prior to April 18, 2019, Congress defined the term "single source drug" to mean "a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration." *Id.* § 1396r-8(k)(7)(iv) (Nov. 5, 1990). Congress recently clarified that definition by deleting the word "original," so that the term "single source drug" now means "a covered outpatient drug which is produced or distributed under a new drug application approved by the Food and Drug Administration," making clear that all that matters is whether a drug is produced or distributed under a new drug application, unless a "narrow exception" spelled out in CMS's regulations applies. *Id*. (Apr. 18, 2019).

The FDA Drug Approval Process

20. Under the Food, Drug, and Cosmetic Act (FDCA), all "new drugs" must be approved by FDA before being introduced or delivered for introduction into interstate

[3] *See, e.g., Ipsen Biopharmaceuticals v. Price*, Civil Action No. 1:16-cv-02372-DLF, ECF 24 (D.D.C. Sept. 24, 2018) at 2 (explaining that "[i]f Somatuline ED is a new drug, Ipsen can calculate and report a new base date AMP for it. If not, Ipsen must continue to use the AMP for the 'old' version of Somatuline Depot Injection.").

commerce. 21 U.S.C. §§ 355(a), 331(d). Generally, a "new drug" is one that is not generally recognized by appropriate experts "as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p). Approval is sought by submission of one of three types of applications: a "new drug application" (NDA), an "abbreviated new drug application" (ANDA), or a "biologics license application" (BLA). *See* 21 U.S.C. §§ 355(b) (governing NDAs), 355(j) (governing ANDAs); 42 U.S.C. § 262(a) (governing BLAs).

21. A "new drug" may be a drug product that has never been approved, or it may be an approved product with a change, such as a new intended use or indication, or a different strength or dosage form. That is because such changes represent a change to the product itself and/or the "conditions prescribed, recommended, or suggested in the [product's] labeling." 21 U.S.C. § 321(p). When such a change is proposed, therefore, the sponsor must obtain FDA approval before marketing and distributing the product with the change. Depending on the nature of the change, such approval is sought by submission of a new NDA, ANDA, or BLA, or a supplement to the already-approved application. *See, e.g.*, FDA, "Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees" (Dec. 2004).[4]

22. For internal tracking purposes, FDA assigns each NDA a six-digit number, referred to as the "NDA number." *See* Drugs@FDA Glossary of Terms (defining "New Drug Application (NDA)" and "New Drug Application (NDA) Number").[5]

[4] *Available at* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf.

[5] *Available at* https://www.fda.gov/drugs/informationondrugs/ucm079436.htm.

23. FDA also assigns an "NDA Classification Code" to each NDA, which "describe[s] FDA's assessment of the relationship of the drug product in the application to its active moieties and to drug products already marketed or approved in the United States." FDA Center for Drug Evaluation and Research Manual of Policies and Procedures, MAPP 5018.2, "NDA Classification Codes" at 9.[6]

CMS Regulations and Guidance Governing "Single Source Drug"

24. In February 2016, CMS finalized a rule relating to the Medicaid Drug Rebate Program. The resulting regulations explain that a "single source drug," for purposes of the agency's regulations and the Medicaid Drug Rebate Program, means:

> [A] covered outpatient drug that is produced or distributed under an original NDA approved by FDA and has an approved NDA number issued by FDA . . . .
>
> For purposes of this definition and the MDR program, an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies.

C.F.R. § 447.502 (definition of "single source drug") (emphasis added).

25. In the preamble to the Final Rule adopting this regulation and in subsequent guidance, CMS confirmed that the "narrow exception" is indeed "very narrow." More pointedly, CMS explained that the exception to the regulatory definition "will not be considered applicable" to drugs "that received patent protection or statutory exclusivity." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170-01, 5192 (Feb. 1, 2016); *accord* CMS, Mfr. Release No. 98, Drug Category Narrow Exception Guidance (May 2, 2016) ("The narrow exception will not

[6] *Available at* https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm470773.pdf. By way of example, a Type 1 NDA is an application seeking approval of a drug that contains a new molecular entity (NME) (*i.e.*, an active ingredient that contains no active moiety that has previously been approved by FDA or marketed in the United States), and a Type 3 NDA is for a new dosage form of an active ingredient that has previously been approved or marketed. *Id.* at 2-3.

be granted under the following circumstances: . . . Drugs that received patent protection or statutory exclusivity, regardless of whether the protection or exclusivity is currently in effect."). The "narrow exception" also "requires" both "the manufacturer's written submission to CMS" and "CMS's response confirming whether or not the exception applies." 81 Fed. Reg. at 5194.

26. Although the Final Rule was published in February 2016 and became effective two months later, CMS made clear during the rulemaking process that the regulatory definition of "single source drug" did not reflect a new agency policy, but instead merely was "designed to clarify existing policy regarding the definitions of original NDA and single source drugs." 81 Fed. Reg. at 5193; *see also id.* at 5196 ("Our proposed language was not designed to change CMS policy, but rather to provide further clarification that an 'original NDA' means an NDA, other than an ANDA, approved by the FDA for marketing, unless the narrow exception discussed above applies.").

Acthar's Approval Under a New NDA

27. H.P. Acthar Gel (as it was known at the time) was first approved by FDA in 1952 under NDA 008372.[7] H.P. Acthar Gel is an injection that contains a naturally occurring hormone, adrenocorticotropic hormone (ACTH). It has been approved by FDA for use in treating more than 50 diseases over the years, including multiple sclerosis and nephrotic syndrome.

28. IS is a rare but devastating seizure disorder occurring in infants and children under the age of two that greatly increases the risk of developmental disability if left untreated. Although H.P. Acthar Gel was not approved to treat IS, physicians started using the product "off

[7] *See* FDA, Drugs@FDA (Approval Date(s) and History, Letters, Labels, Reviews for NDA 008372), available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=008372.

label" for that purpose, because a growing body of evidence, including from published clinical studies, indicated that H.P. Acthar Gel was useful in treating IS. Over time, the product became the treatment of choice for IS. *See, e.g.*, NDA 022432 Summary Review at 1.[8]

29. Questcor acquired H.P. Acthar Gel in 2001, and in 2006 sought to have the product approved for the treatment of IS.[9] The request for approval, which presented information and data from published literature on the use of H.P. Acthar Gel for IS, was submitted as a supplement to the existing NDA (sNDA). In May 2007, FDA issued what is now called a "Complete Response Letter" (CRL), in which the agency declined to approve Questcor's sNDA, explaining that the company had not shown a sufficient nexus between the product and the relied-upon studies to meet the standards for approval.

30. Consistent with FDA procedure, the sNDA remained pending while Questcor and FDA reached agreement on how to address the asserted inadequacy, and the company set about developing the necessary data. During this period, FDA unilaterally converted the sNDA to a new, separate NDA, to which (consistent with standard procedures) the agency assigned a distinct NDA number: NDA 022432. *See* August 8, 2008 FDA Memorandum Re Creating Type 6 NDA.[10] The agency took this action because it concluded the IS indication was fundamentally different from the other uses for which the product had been approved, and required review by a different component within FDA than had to date been responsible for the drug. *Id.* The new

[8] *Available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s0900SumR.pdf (PDF p.2).

[9] The FDA Approval Package for Questcor's application is available online at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432_hp_acthar_gel_toc.cfm.

[10] *Available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s000AdminCorres.pdf (PDF p.69) (explaining that IS indication required review by Division of Neurology Products, not Division of Metabolic and Endocrine Products).

NDA was classified as a "Type 6" NDA, which was used for drug products that had already been approved or marketed by the same applicant, but were intended for a new indication or claim.[11]

31. In December 2009, Questcor provided the information, data, and analysis FDA had identified as necessary for approval, under the separate NDA 022432, seeking approval for H.P. Acthar Gel to treat IS.

32. FDA approved NDA 022432 in October 2010, permitting H.P. Acthar Gel to be marketed and distributed for the treatment of IS. *See* October 15, 2010 FDA Approval Letter for Acthar.[12] In addition to approving the new IS indication, FDA required multiple significant changes to Acthar's labeling. These changes included removing more than 30 previously approved indications, requiring a "risk evaluation and mitigation strategy" (REMS) and a "Medication Guide" for the IS indication, revising certain "Dosage and Administration" information, and adding a new section on pediatric indications.[13]

33. With approval of NDA 022432, FDA also granted Questcor seven years of orphan drug exclusivity, precluding approval of any other entity's NDA, ANDA, or BLA for repository corticotropin to treat IS.

34. FDA acknowledged the grant of orphan exclusivity in a letter dated November 17, 2011, which specifically tied the exclusivity to the new NDA, both by number and by date: "The seven year exclusive approval began on *October 15, 2010, the date of approval of your New*

[11] *Id.*; *see also, e.g.*, MAPP 5018.2 at 5. FDA no longer uses Type 6, instead classifying NDAs that would have fallen into that category as either Type 9 or Type 10. *Id.*

[12] *Available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s000Approv.pdf.

[13] FDA, Achtar Summary Review and Risk Evaluation and Mitigation Strategy, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s0900SumR.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s000REMS.pdf.

Drug Application (22-432)." Exhibit 1 (Nov. 17, 2011 Letter from FDA, a true and correct copy of which is attached hereto) (emphasis added).

35. Acthar's orphan exclusivity continued until October 2017.

CMS Determines in 2012 That Acthar Is a Single Source Drug Entitled to Its Own Base Date AMP

36. In early 2012, Questcor requested permission from CMS to establish a new base date AMP for Acthar. Exhibit 2 (May 8, 2012 Letter from Questcor to CMS, a true and correct copy of which is attached hereto).

37. In that letter, Questcor explained that it was losing money on its participation in the Medicaid Drug Rebate Program because its Medicaid rebate liability exceeded Medicaid revenue for the drug. Because a significant percentage of IS patients are covered by Medicaid, the financial impact on the company from the upside-down rebate-to-revenue delta was significant. And because Questcor effectively was a single-product company, it had no other products to offset those losses.

38. Questcor also acknowledged that the agency might decline to give Questcor the requested new base date AMP. But Questcor noted that without a new base date AMP, "Questcor's continued participation in the MDRP may simply be untenable because that participation generates greater rebate liability and negative revenue for the company." *Id.* at 2. Questcor also noted its belief that "state Medicaid programs likely still will be required to cover Acthar's use for infantile spasms even if Questcor does exit the program." *Id.* In other words, if Questcor exited the MDRP, the Medicaid program would still have to cover Acthar, and Questcor would not have to pay any rebate at all.[14]

[14] The Medicaid statute requires states to cover prescribed drugs under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, defined at 42 U.S.C. § 1905(r), without regard to whether the drug's manufacturer participates in the MDRP. EPSDT is a Medicaid

39. In laying out its request for a new base date AMP, Questcor noted that FDA had said it would be taking steps to associate the IS indication with NDA 008372. Specifically, Questcor advised CMS:

> 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.

Id. at 3 n.4.

40. CMS responded to Questcor's May 2012 letter several months later. Exhibit 3 (August 6, 2012 Letter from CMS to Questcor, a true and correct copy of which is attached hereto). In its response, CMS offered the view that Acthar with the IS indication qualifies for a new base date AMP, specifically citing the FDA approval under a distinct NDA number as the legal basis for the new base date AMP. In doing so, the agency made clear its position that, if a drug product was "approved under" an original NDA, it is treated as a distinct single source drug entitled to its own base date AMP. The agency explained its reasoning as follows:

> Section 1927(c)(2)(A) defines the base date AMP, in part, for each single source or innovator multiple source drug approved by the FDA before or after October 1, 1990. In accordance with that provision, the base date AMP is calculated based on the new drug application which is approved by the FDA, not the national drug code (NDC). Therefore, given that the recently approved Acthar Gel was *approved under a different ND[A]*[15] from the original product, Questcor may set a new base date AMP for this drug.

Exhibit 3 (emphasis added).

41. In September 2012, CMS reiterated its approval—and corrected an error in its prior communication. As the agency explained there, its August letter had "noted that, given that

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benefit that provides all beneficiaries under age 21 with coverage of a comprehensive set of prevention, screening, diagnostic, and treatment services. Acthar is covered under the EPSDT benefit for this population.

[15] While the agency referred to an "NDC" here, instead of an "NDA," that was a scrivener's error, as its subsequent letter (Exhibit 4) confirmed.

Acthar Gel was approved under a different National Drug Code (NDC) from the original product, Questcor Pharmaceuticals may set a new base date AMP for this drug. This was a misstatement on our part. As noted in your letter of May 8, 2012, the FDA approved Acthar Gel through a New Drug Application (NDA) for use in treating the orphan condition of infantile spasms. Accordingly, we would like to correct our earlier reply to note that *because Acthar was approved under a new NDA, Questcor may set a new base date AMP*. We apologize for any confusion." Exhibit 4 (Sept. 19, 2012 Letter from CMS to Questcor, a true and correct copy of which is attached hereto) (emphasis added).

42. Acting in reliance on CMS's statements, Questcor in 2013 began reporting the new Acthar base date AMP.

43. In August 2014, Mallinckrodt acquired Questcor for $5.8 billion, also in reliance on CMS's stated position regarding Acthar's base date AMP.

44. In March 2015, FDA granted Questcor's request—made prior to the Mallinckrodt acquisition—"for the indication for the treatment of infantile spasms to be associated with the parent NDA number 008372, since the tracking NDA number 022432 will no longer be used." *See* March 24, 2015 Letter from FDA to Questcor.[16]

45. Nonetheless, FDA's records continue to reflect that Acthar was *approved* under NDA 022432. Thus, for example, FDA's on-line database Drugs@FDA—which provides "official information about FDA approved innovator and generic drugs"[17]—still lists Acthar as having been approved to treat IS under the second independent NDA number, NDA

[16] *Available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/008372Orig1s044ltr.pdf.

[17] FDA, Drugs@FDA, Frequently Asked Questions, available at https://www.fda.gov/drugs/informationondrugs/ucm075234.htm (last accessed May 17, 2019).

022432.[18] FDA's National Drug Code Directory similarly lists Acthar's NDA number as 022432. *See* FDA, National Drug Code Directory.[19]

46. CMS encourages manufacturers to check both of these official FDA sources to confirm the accuracy of a drug's NDA number before calculating its base date AMP. *See* CMS, Mfr. Release Nos. 80, 82.[20]

47. In addition, Acthar's bulk active ingredient is imported into the United States from Canada under NDA 022432. Exhibit 5 (a true and correct copy of a March 25, 2019 screen shot of electronic records showing an example of importation of bulk active ingredient under NDA 022432).

CMS Begins to Question Its Own 2012 Statements

48. In April 2016, CMS wrote to Mallinckrodt and stated: "It has recently come to our attention that even though [Acthar] is shown to be approved under NDA 022432 on Drugs@FDA, [Acthar] is listed as approved under NDA 008372 on [the] FDA Online Label Repository." Exhibit 6 (April 13, 2016 Letter from CMS to Questcor, and true and correct copy of which is attached hereto).

49. In contrast to the Drugs@FDA website, the "On-Line Label Repository" is based on information submitted by manufacturers that is not verified by FDA. That is why it contains the following "IMPORTANT DISCLAIMER. . . .: The drug labels and other drug-specific information on this Web site represent the most recent drug listing information companies have

[18] FDA, Drugs@FDA, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022432 (last accessed May 17, 2019).

[19] *Available at* https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm (search for "22432" under "Application Number").

[20] *Available at* https://www.medicaid.gov/medicaid/prescription-drugs/program-releases/index.html.

submitted to the Food and Drug Administration (FDA). . . . The drug labeling and other information has been reformatted to make it easier to read but *its content has neither been altered nor verified by FDA.*" *See* FDA Online Label Repository Home Page (emphasis added).[21]

50. CMS's letter continued: "As a result of this discrepancy, we have reviewed the approval status of [Acthar] and it is our understanding that [Acthar] is marketed under NDA 008372 not NDA 022432." CMS also noted that although Acthar's approval letter was assigned NDA number 022432, the approval letter also indicated that most future regulatory submissions should be addressed to NDA 008372. Exhibit 6.

51. CMS's letter requested that Mallinckrodt "review and correct the reporting of its product data in [the Drug Data Reporting for Medicaid (DDR) system] to ensure that accurate information is reported to the MDR program." *Id.* The letter also noted that "the baseline data of an NDC for a single source drug . . . must follow the NDA."

52. After receiving CMS's letter, Mallinckrodt corrected the error on the On-Line Label Repository website, so that it now correctly identifies NDA 022432 as the NDA number under which Acthar was approved.[22] Mallinckrodt also notified CMS that it had done so. Exhibit 7 (July 29, 2016 Email from Mallinckrodt to CMS, a true and correct copy of which is attached hereto).

53. In June 2016, CMS again requested that Mallinckrodt update the "baseline information" for Acthar—but this time for a completely different reason.

[21] *Available at* https://labels.fda.gov/.

[22] *Available at* https://labels.fda.gov/getProprietaryName.cfm (search for "Acthar") (last accessed May 17, 2019).

54. In an email to Mallinckrodt, the agency no longer referred to the Online Label Repository or the Acthar approval letter; instead it referenced a CMS guidance document to argue that "the baseline data of a *purchased product* should be the same as the baseline data of a product marketed under the same NDA." Exhibit 7 (June 2, 2016 Email from CMS to Mallinckrodt, a true and correct copy of which is attached hereto) (emphasis added).

55. The referenced CMS guidance (referred to as "Manufacturer Release #90") relates to treatment of baseline data when manufacturers are buying or selling drug products, including when one drug manufacturer buys a drug product from another drug manufacturer. In other words, CMS appears to have mistakenly thought in June 2016 that Mallinckrodt's purchase of Acthar had supplied the original justification for the new base date AMP.[23]

56. Mallinckrodt explained in response that the cited CMS guidance was inapplicable: "In your email, you indicate that the base date AMP for a 'purchased product' should not be altered. We want to note that Mallinckrodt's purchase of Acthar from Questcor in 2014 was not the basis of CMS's confirmation to Questcor of the appropriateness of a new base date AMP in the agency's letter to Questcor dated August 6, 2012, which was two years before Mallinckrodt's acquisition of Questcor." Exhibit 7 (July 6, 2016 Email from Mallinckrodt to CMS, a true and correct copy of which is attached hereto).

57. Mallinckrodt subsequently made multiple attempts to explain to CMS—in emails, letters, and through an in-person meeting—that its new position was wrong. Exhibit 7; Exhibit 10. CMS offered a new and conflicting view each time. *See* Exhibit 7; Exhibit 8 (March 12, 2019 Letter from CMS to Mallinckrodt, a true and correct copy of which is attached hereto). Although discussions between the parties continued until recently, at no point did CMS reconcile

[23] *Available at* https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-090.pdf.

its 2012 decision with the agency's new position, let alone acknowledge that it had previously taken a different position.

58. On March 27, 2019, CMS informed Mallinckrodt—for the first time—that the agency had "concluded that the April 13, 2016 letter from CMS to Mallinckrodt constituted CMS' final decision on the relevant issue. Therefore, given that there is a final CMS decision on this issue, any meeting . . . would not and could not be productive." Exhibit 11 (March 27, 2019 email from CMS to Mallinckrodt, a true and correct copy of which is attached hereto).

59. Although Mallinckrodt has sought further dialogue with the agency since then, those efforts have been rebuffed. Among other efforts, on April 12, 2019, Mallinckrodt proposed a possible resolution to the agency and requested its consideration of a reasonable path forward.

60. On Friday, May 10, 2019, CMS rejected Mallinckrodt's April 12th proposal and notified the company that unless it updates the base date AMP for Acthar within 14 days—by May 24, 2019—it will be declared "out of compliance" in the DDR. Exhibit 12 (May 10, 2019 Letter from CMS to Mallinckrodt, a true and correct copy of which is attached hereto). That starts the clock ticking: 90 days after the next reporting deadline, Mallinckrodt will automatically be suspended from participating in the Medicaid Drug Rebate Program. 42 U.S.C. § 1396r-8(b)(3)(C)(i). That would cause severe and irreparable harm not just to Mallinckrodt, but also to the public at large, as Medicaid patients with diseases like multiple sclerosis, nephrotic syndrome, and allergic and inflammatory ophthalmic processes could be denied critical access to Acthar.

CMS's Conduct Was Unlawful

61. CMS's apparent determination that Acthar is not a distinct "single source drug" entitled to its own base date AMP violates the Medicaid Drug Rebate statute and CMS's own regulations. It also is arbitrary, capricious, and an abuse of discretion—both because it is inconsistent with the agency's own prior statements in August and September 2012 about single source drugs generally and about Acthar in particular, and because it lacks adequate reasoning. Finally, and most egregiously, CMS's effort to force Mallinckrodt to retroactively "correct" its base date AMP during a time period when the agency was *actively encouraging* Questcor and Mallinckrodt to use the now-disavowed base date AMP violates basic principles of fair notice and due process, as well as the prohibition on retroactive application of new agency policies.

CMS's Decision Violates the Medicaid Drug Rebate Statute

62. First, CMS's new position cannot be reconciled with the statutory text. Until recently, the statute expressly defined "single source drug" to mean "a covered outpatient drug which is *produced or distributed* under an *original new drug application* approved by the Food and Drug Administration." 42 U.S.C. § 1396r-8(k)(7)(iv) (Nov. 5, 1990) (emphases added).

63. The term "original," as used in context of the statute, has a plain and ordinary meaning that requires no particular deference to the agency: it means separate or legally distinct. *See* Black's Law Dictionary (10th ed. 2014) (original: "bearing its own authority, and not deriving authority from an outside source; as original jurisdiction, original writ").

64. More recently, Congress clarified this meaning *by deleting the term "original"* from the definition of "single source drug," making abundantly clear that all that is required to trigger a new base date AMP is a distinct NDA, unless the "narrow exception" spelled out in CMS's regulation applies (and here it undisputedly does not).

65. Thus, a drug produced or distributed under a distinct NDA must be treated as a "single source drug."

66. Acthar is approved under a distinct NDA, NDA 022432. Acthar is a "new drug" that could not have been lawfully marketed for treatment of IS without FDA approval. 21 U.S.C. § 355(a). That approval was obtained via NDA 022432.

67. Acthar is also "produced or distributed" under that distinct NDA. When FDA recognized Acthar's orphan drug exclusivity for treatment of IS in November 2011, it did so under NDA 022432. Exhibit 1. The product was distributed under the protection of that exclusivity until 2017, when the exclusivity expired. To this date, Mallinckrodt imports the bulk active ingredient for Acthar into the United States from Canada under NDA 022432. Exhibit 5. And not only that; Acthar is listed on Drugs@FDA and the NDC Directory—sources CMS specifically references in agency guidance regarding identification of the appropriate NDA number—under NDA 022432.

68. CMS acknowledged that the "produced or distributed under" question is effectively coterminous with an "approved under" inquiry when it took the position in its 2012 letters to Questcor that what matters is the NDA number under which the drug product is *approved.* Exhibit 3 (Aug. 6, 2012 Letter from CMS to Mallinckrodt)(emphases added); *see also* Exhibit 4 (Sept. 19, 2012 Letter from CMS to Mallinckrodt) (reiterating CMS's conclusion that "because Acthar was approved under a new NDA, Questcor may set a new base date AMP").

69. Because Acthar is produced or distributed under a distinct NDA, it is a "single source drug" eligible for its own base date AMP under the plain meaning of the statute. CMS's decision therefore was in error and should be overturned.

CMS's Decision Violates the Agency's Regulations

70. CMS's decision also is unlawful because it violates the agency's own regulations. CMS has bound itself through notice-and-comment rulemaking to the position that a "single source drug" means a "covered outpatient drug that is produced or distributed under an original NDA approved by FDA and has an approved NDA number issued by FDA," and that an "original NDA" means "an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies." 42 C.F.R. § 447.502.

71. CMS has made clear that the "narrow exception" does not apply to "drugs that received patent protection or statutory exclusivity," nor can it be applied without "the manufacturer's written submission to CMS, and CMS's response confirming that the exception applies." *See* 81 Fed. Reg. at 5191–92.

72. Based on CMS's formally adopted and clearly enunciated standard, there can be no dispute that NDA 022432 is an original NDA. It is "an NDA, other than an ANDA, approved by the FDA for marketing." The "narrow exception" cannot apply, because Acthar received orphan exclusivity for the IS indication with the approval of NDA 022432. Nor could there be any real dispute that Acthar is "produced" and "distributed" under NDA 022432, for the reasons explained above. Acthar therefore is a distinct "single source drug" entitled to its own base date AMP under CMS's own regulations. CMS's decision to the contrary thus conflicts with the agency's own regulation, and is unlawful.

CMS's Decision Is Arbitrary and Capricious.

73. CMS's decision that Acthar is not a distinct single source drug entitled to a new base date AMP also is arbitrary, capricious, and an abuse of discretion because without offering

any explanation, it abruptly reversed the agency's prior position—as expressly confirmed in writing to Questcor in 2012—that Acthar is precisely such a drug.

74. In its April 13, 2016, letter , which CMS characterized nearly three years later as its "final decision on the relevant issue," the agency gave *no* explanation at all—let alone an adequate one—for its abrupt change of position.

75. And even though the agency continued to communicate with Mallinckrodt on the issue for years, those communications were themselves insufficient to substantiate the agency's position. To this day, despite Mallinckrodt's multiple requests for an explanation of CMS's changed position, CMS has offered only scant and evolving reasoning for it.

76. Nor is there any good reason that CMS *could* give for its change of position: Acthar must be treated as a distinct single source drug because it *is* a distinct single source drug, both under the plain language of the statute and under CMS's own binding regulations.

CMS's Change in Position Violates Basic Principles of Fair Notice, Due Process, and the Prohibition on Retroactive Applications of New Agency Positions.

77. Finally, CMS's flip-flop on whether Acthar is entitled to its own base date AMP contravenes core principles of fair notice, due process, and the prohibition on inequitable retroactive application of new agency policies.

78. The agency's request that Mallinckrodt "correct" the base date AMP for Acthar means that Mallinckrodt will be subjected, retroactively, to higher rebates on the drug product. State Medicaid agencies will automatically be notified of the increased unit rebate amounts resulting from the change in the base date AMP. The manufacturer is then responsible for making adjustments to account for any underpayments in those past periods; failure to do so might result in potential termination of its National Drug Rebate Agreement (NDRA) and/or further enforcement proceedings. 83 Fed. Reg. 12,770, 12,776 (Mar. 23, 2018).

79. As the agency put it to Mallinckrodt during the parties' ongoing discussions: "Once Mallinckrodt certifies the corrected information, states will receive notification on the subsequent rebate file, in the form of prior period adjustments, which indicate that the [URA] has changed for the drug. Mallinckrodt will be responsible for adjusting previous payments to the states using the Prior Quarter Adjustment Statement (PQAS) in accordance with the URA changes." Exhibit 9 (Nov. 6, 2018 Letter from CMS to Mallinckrodt).[24]

80. Mallinckrodt, and Questcor before it, relied in good faith on CMS's express pronouncements in August and September 2012 that Acthar is entitled to its own base date AMP and that the relevant question was whether the drug product was "approved under" an original NDA. Indeed, as Questcor made clear in its contemporaneous communications with the agency, Questcor's continued participation in the Medicaid Drug Rebate Program would have been "untenable" if CMS had not affirmatively permitted it to establish a new base date AMP in 2012. Exhibit 2 (May 8, 2012 Letter) at 2. And, as Questcor also noted at the time, if that had happened, Acthar with the IS indication likely would have continued to be covered by Medicaid, but Questcor would not have had to pay rebates at all—let alone rebates in the higher amounts that CMS is now seeking.

81. In keeping with basic principles of fair notice and due process, CMS cannot now seek back payment or take enforcement action against Mallinckrodt for relying on the agency's own clear pronouncements about Acthar's base date AMP. *See, e.g., FCC v. Fox Television Stations, Inc.*, 567 U.S. 239 (2012); *see also SNR Wireless LicenseCo, LLC v. FCC*, 868 F.3d 1021, 1043 (D.C. Cir. 2017) ("It is a basic principle of administrative law that an agency cannot

[24] CMS subsequently agreed to "refrain from taking action on [Acthar]" until after a meeting that had been scheduled between Mallinckrodt and CMS, *see* Exhibit 10 (November 30, 2018 email from CMS to Mallinckrodt, a true and correct copy of which is attached hereto).

sanction an individual for violating the agency's rules unless the individual had 'fair notice' of those rules.").

82. Similarly, under the retroactivity principles set forth in the D.C. Circuit's *Retail Union* decision and its progeny, CMS cannot apply its new interpretation of "single source drug" retroactively, after Questcor and Mallinkrodt relied in good faith on an earlier interpretation expressly articulated by CMS and specifically applied to Acthar. *See Retail, Wholesale, and Dep't Store Union, AFL-CIO v. NLRB*, 466 F.2d 380 (D.C. Cir. 1972).

83. Before April 2016, CMS *actively encouraged* Questcor and Mallinckrodt to use a new base date AMP for Acthar. CMS plainly is prohibited from applying its new position retroactively to that time period. Exhibit 3; Exhibit 4.

84. Moreover, even to this date, CMS has failed to explain its change in position; instead, the agency has issued sporadic and evolving rationales for its assertion that Acthar is not entitled to a new base date AMP. A regulated entity cannot be said to have received fair notice of an action when the agency itself cannot settle on a justification for it.

Mallinckrodt and Medicaid Patients Who Rely Upon Access to Acthar Will Suffer Immediate and Irreparable Harm Absent Injunctive Relief.

85. Absent immediate judicial relief, Mallinckrodt and Medicaid patients who rely upon access to Acthar will suffer severe and irreparable harm.

86. CMS has threatened to declare Mallinckrodt "out of compliance" in the DDR system if Mallinckrodt does not change the base date AMP by **May 24, 2019**. Exhibit 12 (May 10, 2019 Letter from CMS to Mallinckrodt). CMS spelled out for Mallinckrodt the consequences of that: "When a [drug product] is identified as out of compliance, the submission of pricing records or updates to product data will not be allowed online or via file transfer." *Id.*

In other words, when Mallinckrodt is declared "out of compliance," it will not be able to report or revise drug pricing data in the DDR system.

87. Under the Medicaid drug rebate statute, when a manufacturer fails to report pricing data within ninety days of a deadline, its National Drug Rebate Agreement (NDRA) is suspended for a period of at least thirty days. 42 U.S.C. § 1396r-8(b)(3)(C)(i). And because it is the NDRA that triggers states' obligation to cover a manufacturer's covered outpatient drugs, if Mallinckrodt's NDRA is suspended, states would no longer be required to cover Acthar.

88. That, in turn, would mean that Medicaid patients in dire need of the drug—including patients with multiple sclerosis, nephrotic syndrome, allergic and inflammatory ophthalmic processes—could lose crucial access to Acthar.

89. CMS also threatened to refer Mallinckrodt to the Department of Justice and/or the Office of Inspector General of the Department of Health and Human Services (HHS-OIG). Exhibit 12.

90. When CMS carries through on its threats, the consequences will be devastating to Mallinckrodt: it will be frozen out of participation in the Medicaid Drug Rebate Program entirely, and may be subject to further penalty (including civil monetary penalties).

91. In addition, Mallinckrodt faces imminent and irremediable harm to its reputation, goodwill, and market standing as a result of being wrongly identified by CMS as "out of compliance" with DDR requirements and subject to threat of an extraordinary loss of revenue.

92. Mallinckrodt also faces direct, substantial, and irremediable harm in the form of being subject to an unlawful enforcement action.

93. Finally, yet most importantly, if Mallinckrodt's NDRA is suspended, Medicaid patients with serious medical conditions could be denied critical access to Acthar, because states will no longer be required to cover the drug product.

COUNT I
(Administrative Procedure Act, 5 U.S.C. §§ 700, *et seq.*)

94. Mallinckrodt re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

95. The APA prohibits CMS from carrying out the agency's statutory and regulatory duties in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to a constitutional right. *See* 5 U.S.C. § 706(2).

96. CMS's determination that Acthar is not a distinct "single source drug" entitled to its own base date AMP was unlawful, arbitrary, and capricious.

97. CMS's determination that Acthar is not a distinct "single source drug" entitled to its own base date AMP violates the Medicaid Drug Rebate Statute.

98. CMS's determination that Acthar is not a distinct "single source drug" entitled to a new base date AMP violates the agency's own governing regulations.

99. CMS's determination that Acthar is not a distinct "single source drug" entitled to a new base date AMP was procedurally improper. Among other things, CMS acted unlawfully in altering the legislative policies set forth in its regulations (including but not limited to 42 C.F.R. § 447.502) without engaging in notice-and-comment rulemaking.

100. CMS's determination that Acthar is not a distinct "single source drug" entitled to a new base date AMP is arbitrary, capricious, and an abuse of discretion because it is directly contrary to the position previously taken by CMS in its guidance document and in its August and

September 2012 letters to Questcor. CMS has failed to offer an adequate explanation for its abrupt change in position.

101. CMS's determination that Acthar is not a distinct "single source drug" entitled to a new base date AMP also is arbitrary and capricious because it reflects a failure of reasoned decisionmaking.

102. CMS's determination that Acthar is not a distinct "single source drug" entitled to a new base date AMP—and in particular its effort to seek back-payment and take enforcement action against Mallinckrodt—violates basic notions of fair notice and retroactive rulemaking.

103. CMS's decision that Acthar is not a distinct single source drug entitled to a new base date AMP—particularly when coupled with its assertion that its April 2016 letter constituted the agency's "final decision," its imposition of a firm deadline for compliance, and its explicit threat of an enforcement action—constitutes final agency action for which Mallinckrodt has no other adequate remedy within the meaning of 5 U.S.C. § 704. It would be futile for Mallinckrodt to avail itself of any remaining administrative review. CMS has admitted as much, and in fact has refused any further discussions or agency review.

104. Both Mallinckrodt and the public would be irreparably harmed if CMS's decision were allowed to stand.

105. Mallinckrodt is without an adequate remedy at law.

106. The intent of Congress and the public interest will be served by an Order directing CMS to treat Acthar with the IS indication as a distinct single source drug entitled to its own base date AMP.

COUNT II
(Fair Notice/Due Process)

107. Mallinckrodt re-alleges and incorporates by reference the allegations in the foregoing numbered paragraphs.

108. In 2012, CMS expressly informed Questcor that Acthar is a distinct single source drug entitled to a new base date AMP.

109. Mallinckrodt—and Questcor before it—relied in good faith on the positions articulated by CMS in its 2012 letters to Questcor. Indeed, as Questcor made clear in its contemporaneous communications with the agency, Questcor would have left the Medicaid Drug Rebate Program entirely if CMS had not affirmatively permitted it to establish a new base date AMP in 2012.

110. CMS's failure to give Mallinckrodt advance notice of its newfound interpretation of "single source drug" violates basic principles of fair notice. *See, e.g., FCC v. Fox Television Stations, Inc.*, 567 U.S. 239 (2012); *SNR Wireless LicenseCo, LLC v. FCC*, 868 F.3d 1021, 1043 (D.C. Cir. 2017); *General Elec. Co. v. EPA*, 53 F.3d 1324, 1328–29 (D.C. Cir. 1995).

111. In addition, CMS's effort to seek enforcement action against Mallinckrodt and/or to seek corrective payment retroactively violates the procedural due process guarantees of the Fifth Amendment to the United States Constitution and the APA.

PRAYER FOR RELIEF

For the foregoing reasons, Mallinckrodt prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that CMS's determination that Acthar is not a distinct "single source drug" entitled to its own base date AMP violates the Medicaid drug rebate statute, the Administrative Procedure Act, the

fair notice doctrine, and/or the Fifth Amendment's Due Process Clause, and is unenforceable to the extent it does so;

B. An order vacating and setting aside CMS's determination that Acthar is not entitled to a new base date AMP;

C. Temporary, preliminary, and permanent injunctive relief barring Defendants and any entities acting in concert with them from suspending Mallinckrodt from the MDRP and/or taking any other action, including enforcement action, against Mallinckrodt based on CMS's determination that Acthar is not a distinct "single source drug" entitled to a new base date AMP within the meaning of the Medicaid drug rebate statute.

D. An order awarding Mallinckrodt its costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

E. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Catherine E. Stetson

Catherine E. Stetson (D.C. Bar No. 453221)
Susan M. Cook (D.C. Bar No. 462978)
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004
Phone: (202) 637-5491
Fax: (202) 637-5910
cate.stetson@hoganlovells.com

Counsel for Mallinckrodt ARD LLC

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