UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MALLINCKRODT ARD LLC,

Plaintiff,

v.

SEEMA VERMA, *et al.*,

Defendants.

Civil Action No. 19-cv-1471 (TFH)

UNDER SEAL

MEMORANDUM OPINION

Plaintiff Mallinckrodt ARD LLC filed this lawsuit challenging the Centers for Medicare & Medicaid Services' (CMS's) conclusion that Mallinckrodt is using the wrong base date Average Manufacturer Price (AMP) to calculate federally mandated rebates it must pay for the H.P. Acthar Gel® pharmaceutical drug under the statutory Medicaid Drug Rebate Program. Defendants Seema Verma, Administrator of CMS, and Alex M. Azar II, Secretary of the United States Department of Health and Human Services (HHS), counter by alleging that Mallinckrodt has been underpaying the required rebates and depriving Medicaid of hundreds of millions of dollars since 2013.

Pending before the Court are the following three motions: (1) Mallinckrodt's Motion for Preliminary Injunction, ECF No. 4; (2) Government's Motion for Summary Judgment, ECF No. 17; and (3) Mallinckrodt's Cross Motion for Summary Judgment, ECF No. 22. Because there are no material facts in dispute and CMS lawfully determined that the Medicaid Drug Rebate Program statute requires that Acthar's base date AMP be calculated based on the date the drug was approved by the United States Food and Drug Administration (FDA) under New Drug

Application (NDA) number 008372, the Court will deny Mallinckrodt's motions and grant the defendants' motion.

STATUTORY AND REGULATORY STRUCTURE

Mallinckrodt ARD LLC is a pharmaceutical company that markets and sells a drug called H.P. Acthar Gel® (Acthar), which is an adrenocorticotropic hormone (ACTH) analogue derived from pigs' pituitary glands. Administrative Record ("A.R.") 28, 182. Mallinckrodt acquired Acthar in 2014 when it purchased the drug's prior manufacturer, Questcor Pharmaceuticals. A.R. 54. Many of the relevant events in this case occurred while Questcor reigned as Acthar's manufacturer before merging with Mallinckrodt. At issue is whether CMS lawfully determined that Questcor and Mallinckrodt have been miscalculating Acthar's Medicaid rebates since 2013.

Resolving this issue implicates two federal statutes that are administered by operating divisions of HHS. The first statute is the Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 *et seq.*), which governs drug applications and is administered by the United States Food and Drug Administration (FDA).[1] The second statute is Title XIX of the Social Security Act, 79 Stat. 343 (codified as amended at 42 U.S.C. §§ 1396–1396v), which is commonly known as the "Medicaid Act." The Medicaid Act establishes the Medicaid Drug Rebate Program and specifies how drug rebates must be calculated. *See* 42 U.S.C. § 1396r-8. The Medicaid Act and Medicaid Drug Rebate Program are administered by CMS. *See Moore ex rel. Moore v. Reese*, 637 F.3d 1220, 1235 (11th Cir. 2011) (stating that

[1] Many documents in the Administrative Record contain acronyms. For ease, and to avoid taxing the reader's memory about what a particular acronym means, the Court will avoid using all but the most readily recognized acronyms, such as CMS, HHS, FDA, and NDA. The first time the Court mentions a phrase that is referred to in the record by acronym, however, the associated acronym will be identified for cross reference even though that acronym might not be used again in this opinion.

CMS "is charged with administering the Medicaid Act"). Because it is important to understand the process to obtain FDA approval for new drugs, and labeling changes to add new indications for previously approved drugs, as well as how the Medicaid Drug Rebate Program works, the Court will begin with a brief discussion of both the Federal Food, Drug, and Cosmetic Act and the Medicaid Act before proceeding to discuss the facts and the Court's analysis of the legal issues.

I. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS IMPLEMENTING REGULATIONS

Section 505 of the Federal Food, Drug, and Cosmetic Act requires companies to apply for FDA approval before marketing a "new drug" commercially. 21 U.S.C. § 355(a); *accord United States v. Rutherford*, 442 U.S. 544, 551 (1979) ("By its terms, § 505 of the Act requires premarketing approval for 'any new drug' unless it is intended solely for investigative use or is exempt under one of the Act's grandfather provisions."). The Act defines "new drug" in relevant part to mean "[a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p).

A drug manufacturer may apply to the FDA for approval to market a new drug after the manufacturer obtains sufficient evidence about the drug's safety and effectiveness to satisfy the FDA's requirements. *See* New Drug Application (NDA), Drugs@FDA Glossary of Terms, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms. The application for a new drug is subject to certain conditions and procedures outlined in the Federal Food, Drug, and Cosmetic Act and the regulations that implement that Act. *See* 21 U.S.C. § 355(b); 21 C.F.R. §§ 314.50–314.99.

Although there are three types of drug marketing applications, the only one that is relevant here is the type generically titled "New Drug Application" and referred to by the acronym "NDA."[2] The Federal Food, Drug, and Cosmetic Act's regulations define the terms "new drug application, or NDA" to mean in relevant part "the application described under [21 C.F.R.] § 314.50, including all amendments and supplements to the application." 21 C.F.R. § 314.3(b). 21 C.F.R. § 314.50, in turn, is the federal regulation that sets forth the required contents and format for NDAs and their supplements. 21 C.F.R. § 314.50 (stating that "NDAs and supplements to approved NDAs are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section"). As indicated, the statute and regulation contemplate that an NDA includes later amendments or supplements rather than treating amendments or supplements as independent NDAs. 21 U.S.C. § 355(b); 21 C.F.R. § 314.50.

As will become clear, much of the dispute in this case revolves around numbers the FDA assigns to NDAs and their supplements. When manufacturers like Mallinckrodt and Questcor submit an NDA the FDA assigns the application a six-digit number. *See* New Drug Application (NDA) Number, Drugs@FDA Glossary of Terms, https://www.fda.gov/ drugs/drug-approvals-and-databases/drugsfda- glossary-terms (defining "New Drug Application Number" to mean a "six digit number . . . assigned by FDA staff to each application for approval to market a new drug in the United States"). "A drug can have more than one application number if it has

[2] The other two types of applications are Abbreviated New Drug Applications (ANDAs), which are governed by § 505(j) of the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and Biologic License Applications (BLAs), which are governed by § 351 of the Public Health Service Act (PHSA), 42 U.S.C. § 262(a), and its implementing regulations.

different dosage forms or routes of administration." *Id.* The FDA assigns NDA numbers "[f]or internal tracking purposes." *Id.*

When a company seeks to "make changes" to a drug "that already has an approved new drug application (NDA)" the company may do so by submitting a "supplement" application to the FDA's Center for Drug Evaluation and Research (CDER). Supplement, Drugs@FDA Glossary of Terms, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms. The Center for Drug Evaluation and Research "must approve all important NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still met."[3] *Id.*

Important to this case, when a drug manufacturer seeks to add a new indication[4] for a drug that has an existing FDA-approved NDA and number, the Federal Food, Drug, and Cosmetic Act's implementing regulations contemplate that the request will be presented as an "efficacy supplement," which is defined to mean, in relevant part, a "supplement to an approved NDA proposing to . . . [a]dd or modify an indication or claim." 21 C.F.R. § 314.3(b). A "supplement" is assigned a "supplement number" that is "associated with an existing FDA New Drug Application (NDA) number." Supplement Number, Drugs@FDA Glossary of Terms, https://www.fda.gov/ drugs/drug-approvals-and-databases/drugsfda-glossary-terms. The supplement number "is usually, but not always, sequential, starting with 001." *Id.*

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[3] The FDA's Center for Drug Evaluation and Research has numerous offices and divisions, including the Division of Metabolism and Endocrinology Products (DMEP) and the Division of Neurology Products (DNP). CDER Offices and Divisions, U.S. Food and Drug Administration, https://www.fda.gov/about-fda/center-drug-evaluation-and-research/cder-offices-and-divisions.

[4] An "indication" identifies "what the drug is used for." Label, Drugs@FDA Glossary of Terms, https://www.fda.gov/drugs/ drug-approvals-and-databases/ drugsfda-glossary-terms.

In addition to the Federal Food, Drug, and Cosmetic Act and its implementing regulations, the FDA circulates additional guidance about matters related to NDAs in the form of various agency manuals for industry. One such document is the Guidance for Industry Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees ("Guidance for Industry"). A.R. 898–907. As the FDA explains in the Guidance for Industry, "[b]ecause different user fees are assessed for original applications and supplements, FDA believes it is useful to provide guidance to applicants on the Agency's interpretation of what constitutes a separate original application, amendment, or supplement." A.R. 902. Notably, the Guidance for Industry instructs drug manufacturer's that changes to an approved drug to add a new indication "should be submitted individually in a separate *supplement* to an approved original application." A.R. 906 (emphasis added).

Another example of an FDA document that provides guidance about NDAs is the Center for Drug Evaluation and Research's Manual of Policy and Procedures (MAPP). A.R. 936–45. That manual "describes the new drug application (NDA) classification code assigned by the Center for Drug Evaluation and Research (CDER) to an NDA based on characteristics of the product in the application." A.R. 936. The classification code is different from the NDA number, *see* A.R. 937 – 42 (identifying the various current and obsolete codes), and "provides a way of categorizing new drug applications . . . including their relationships to products already approved or marketed in the United States," A.R. 936. The Manual of Policy and Procedures states that it is the FDA's policy to "tentatively assign[] an NDA classification code by the filing date for a new application and reassess[] the code at the time of approval." A.R. 936. "The reassessment will be based upon relationships of the drug product being approved to products

already approved or marketed in the United States at the time of approval." A.R. 936–37. "FDA may also reassess the code after approval." A.R. 937.

The version of the Manual of Policy and Procedures that was submitted as part of the Administrative Record in this case identifies the NDA classification codes to be Type 1 through Type 10. A.R. 937–42. The only NDA classification code that is relevant here is Type 6, which the Manual explains is now obsolete but was used through July 2009 "for a drug product that duplicates a drug product already approved or marketed in the United States by the same applicant, except that it is intended for a new indication or claim (same active moiety or combination of active moieties, same salt(s), ester(s), or other noncovalent derivative(s), same dosage form, and same formulation (including all ingredients used in the manufacturing process whether or not they are present in the final dosage form))." A.R. 940 & n.5 (noting that "July 27, 2009 is the date of implementation of the Document Archiving, Reporting and Regulatory Tracking System (DARRTS), which made *Type 6* obsolete" (emphasis in original)).

II. THE MEDICAID ACT AND THE MEDICAID DRUG REBATE PROGRAM

After the FDA approves a new drug under the Federal Food, Drug, and Cosmetic Act, the drug's manufacturer (also referred to as the drug's "labeler") may seek to have the drug covered by Medicaid through the Medicaid Drug Rebate Program. *See* Medicaid National Drug Rebate Agreement, CMS, https://www.medicaid.gov/ medicaid/prescription-drugs/medicaid-drug-rebate-program/national-drug-rebate-agreement/index.html (discussing the requirements and process to request a Medicaid National Drug Rebate agreement). "Medicaid, as everyone knows, is a cooperative state-federal program designed to provide medical assistance to poor people." *Indiana Family & Soc. Servs. Admin. v. Thompson*, 286 F.3d 476, 477 (7th Cir. 2002). It was established in 1965 when Congress amended the Social Security Act by adding Title XIX.

Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 650 (2003). Each state establishes its own Medicaid plan but plans that are approved by the federal government are eligible to receive federal matching funds. *Indiana Family & Soc. Servs. Admin.*, 286 F.3d at 477.

The Medicaid Drug Rebate Program—which, as already explained, is administered by CMS—is set forth in the Medicaid Act and serves to offset federal and state agencies' costs for covered outpatient drugs prescribed to Medicaid patients. 42 U.S.C. § 1396r-8(b); *see* Verified Compl. ¶ 16, ECF No. 1 (averring that drug manufacturers are required to "pay greater rebate amounts where price increases outpace the rate of inflation"). To participate in the Medicaid Drug Rebate Program a drug must be a "covered outpatient drug" as defined in the Medicaid Act and its manufacturer must have a rebate agreement with the Secretary of HHS. 42 U.S.C. §§ 1396r-8(a)(1), (k)(2)–k(4). Rebate agreements afford Medicaid coverage for qualifying drugs but mandate that the drug's manufacturer provide a rebate to participating states to reduce the costs of dispensed outpatient drugs that a state expends under its Medicaid plan. 42 U.S.C. § 1396r-8(b)(1)(B).

The Medicaid Act mandates how drug manufacturers must calculate the amount of rebate for "each dosage form and strength of a single source drug" under the Medicaid Drug Rebate Program. 42 U.S.C. § 1396r-8(c)(1)(A). A "single source drug" is defined in relevant part to mean a drug that is "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). The Medicaid Act's implementing regulations state more particularly 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." 42 C.F.R. § 447.502. The regulations further state that "[f]or 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."[5] *Id.*

The Medicaid Act and its implementing regulations do not define "new drug application" or "NDA." As already discussed, however, the Food, Drug, and Cosmetic Act's implementing regulations define those terms to mean "the application described under § 314.50" including "all supplements to the application." 21 C.F.R. § 314.3(b). Accordingly, to summarize, a drug manufacturer must calculate the required rebate for each dosage form and strength of a covered outpatient drug that is being produced or distributed under an FDA-approved new drug application, as described in 21 U.S.C. § 314.50, including all supplements.

The calculated rebate amount for single source drugs is referred to as a "unit rebate amount (URA)" and consists of a basic rebate plus an additional rebate. 42 U.S.C. §§ 1396r-8(c)(1), (c)(2). The basic rebate amount equals the number of a drug's units the state paid for under its Medicaid plan multiplied by the greater of (1) the AMP minus the best price for the drug or (2) a statutorily set minimum rebate percentage of the drug's AMP. 42 U.S.C. § 1396r-8(c)(1). The additional rebate is the amount, if any, that the drug's AMP for a particular quarter exceeded the so-called "base date AMP," which is a covered outpatient drug's AMP for the third quarter of 1990 if the drug was FDA-approved on or before October 1, 1990, or the AMP for the

[5] In a response to comments accompanying CMS's issuance of a final rule implementing provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "Affordable Care Act"), the agency stated that the narrow exception involves circumstances in which "for the purposes of the Medicaid Drug Rebate (MDR) program, certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5,170, 5,191 (Feb. 1, 2016) (to be codified at 42 C.F.R. § 447).

first full quarter of sales if the drug was FDA-approved after that date, either of which is adjusted by an inflation factor. 42 U.S.C. § 1396r-8(c)(2).

As the plaintiff concedes, "the base date AMP is generally used to calculate Medicaid rebates for the entire life of the relevant drug product." Verified Compl. ¶ 1.

BACKGROUND

I. H.P. ACTHAR GEL'S FDA APPROVAL UNDER ORIGINAL NDA NUMBER 008372 AND EFFICACY SUPPLEMENT APPROVAL UNDER NOW DEFUNCT NDA NUMBER 022432

A. In 1952, the FDA Approved H.P. Acthar Gel to be Marketed as a New Drug Under NDA Number 008372

Approximately 70 years ago, H.P. Acthar Gel's original manufacturer applied to the FDA for approval to market the drug commercially in the United States. A.R. 51.[6] The FDA assigned the application a six-digit NDA number, which was 008372. A.R. 51. At that time—unlike today—"drug manufacturers only had to show the drug was safe for use in humans" without proving the drug's efficacy.[7] A.R. 509.

In 1952, the FDA approved NDA number 008372, which allowed Acthar's manufacturer to market the drug to treat about 50 indications.[8] A.R. 29, 183, 355, 859. Infantile spasms (IS) was not one of the approved indications. A.R. 183. By 1958, however, Acthar was regarded as a

[6] Indicating that Acthar was approved in 1952, in which case the application was filed no later than that year.

[7] *See United States v. Sage Pharm., Inc.*, 210 F.3d 475, 478 (5th Cir. 2000) (stating that, "[i]n 1962, the [Federal Food, Drug, and Cosmetic Act] was amended to require NDAs to show that a drug is not only safe, but also effective for its intended uses").

[8] According to the FDA, a "label is the official description of a drug product [that] includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient."

successful off-label treatment for the disease. A.R. 29. Indeed, over time, Acthar became the premier treatment for infantile spasms. A.R. 29, 344, 735.

Over the course of several decades, Acthar's NDA number 008372 was the subject of numerous supplement applications to make labeling and other changes, including expanding Acthar's label indications to add the treatment of multiple sclerosis. *See* A.R. 52 (indicating that Acthar was never assigned a different NDA number until 2008), 723–26 (identifying supplement applications), 859 (stating that Acthar's label was expanded in 1972 to include multiple sclerosis). The drug's use to treat infantile spasms, however, continued to be off label. *See* A.R. 754 (noting "the continued off-label use of Acthar Gel" for infantile spasm treatment through 2010).

B. In 2006, Questcor Unsuccessfully Submitted an Efficacy Supplement to Add Infantile Spasms to Acthar's Label Indications

By 2003, Questcor owned Acthar and sought FDA approval to have the drug designated an "orphan drug" to treat infantile spasms.[9] A.R. 710 (referring to Questcor's February 24, 2003 request). The Office of Orphan Products Development granted the requested orphan drug designation via a letter dated May 21, 2003. A.R. 710–11. The letter stated, however, that final approval to market Acthar as an orphan drug would be reserved until Questcor secured FDA approval to market Acthar to treat infantile spasms. A.R. 710.

Three years later, Questcor submitted an application to the FDA seeking approval to market Acthar as an infantile spasm treatment by adding that indication to the drug's existing

[9] An "orphan drug" is a drug "intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug." Office of Orphan Products Development, U.S. Food and Drug Administration, https://www.fda.gov/about-fda/office-special-medical-programs/office-orphan-products-development.

label. A.R. 65 (stating that "[t]his supplemental application proposes to add the treatment of infantile spasms to reduce or eliminate spasms and the hypsarrhythmic electroencephalogram pattern to the indications and usage section of the package insert for H.P. Acthar® Gel") (formatting omitted), 577 (stating that Acthar's label would be expanded by "adding the indication of infantile spasms"), 856. A.R. 65. The application was dated June 16, 2006 and was submitted to the FDA's Division of Metabolism and Endocrinology Products. A.R. 65, 856. Questcor's application was presented as an "efficacy supplement" to NDA number 008372. A.R. 188, 694, 735, 891. The FDA assigned the application Supplement Number S-039. A.R. 694, 735, 891.

On May 10, 2007, the FDA's Division of Metabolism and Endocrinology Products rejected Questcor's application by issuing a "Not Approvable" letter that cited "numerous deficiencies, including the lack of a bridge between this specific product and the products used in the various published studies." A.R. 344; *accord* A.R. 65–67, 856. Significantly, the Not-Approvable letter stated that the Division of Metabolism and Endocrinology Products had conferred with epilepsy subject-matter experts at the agency's Division of Neurology Products and determined that the Division of Neurology Products "should have regulatory and scientific oversight" of Questcor's application. A.R. 66.

C. In 2009, Questcor Resubmitted the Efficacy Supplement Application and the FDA Assigned it an NDA Number for Administrative Tracking and to Facilitate the FDA Division of Neurology Products' Review

After the Not-Approvable letter notified Questcor that the Division of Neurology Products should be handling the efficacy supplement application, Questcor began conferring with that division about how to resubmit the application to secure FDA approval. *See* A.R. 189, 344, 875, 869. Questcor ultimately resubmitted the application on December 10, 2009. A.R. 869.

The Division of Neurology Products viewed Questcor's resubmission to be a "response" to the FDA's May 10, 2007 Not-Approvable letter and "redesignated" it as a "Type 6 NDA" for that division's review. A.R. 344, 856–57, 869. A contemporaneous file memorandum that discussed changing the resubmission's regulatory classification noted that a "Type 6 NDA" was "an efficacy supplement that is designated . . . as a new NDA and assigned a new NDA number for administrative purposes (e.g., to facilitate the review of a supplement for an indication *for which the scientific expertise lies in a division different from the parent division for the original application*)." A.R. 857 n.* (emphasis added). And a later email from the FDA to a CMS official confirmed that the agency "created Type-6 NDAs when an efficacy supplement was submitted for an indication to be reviewed by [a] Division other than the Division responsible for the parent (original) NDA to ensure that all of the documents submitted for review in support of a new indication would be sent to the appropriate Division." A.R. 157. The FDA explained that "[i]n the case of Acthar Gel, the parent NDA (008372) and all of its supplements were reviewed by the Division of Metabolic and Endocrine Products and review of the infantile spasms indication was conducted by the Division of Neurology Products." A.R. 157.

Mallinckrodt agrees that "[t]he agency took this action because it concluded the IS [infantile spasm] 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." Verified Compl. ¶ 30. Mallinckrodt also does not dispute that the Type 6 designation "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." Verified Compl. ¶ 30 (emphasis added).

The FDA assigned an administrative tracking number—NDA number 022432—to the resubmission. A.R. 708.

D. In 2010, The FDA Approved Questcor's Efficacy Supplement Application to Add Infantile Spasms to Acthar's Label and Directed Questcor to Stop Using NDA Number 022432 in Favor of Acthar's Original NDA Number 008372

In 2010, the FDA approved Questcor's efficacy supplement application to add infantile spasms to Acthar's label indications. A.R. 702–707. Importantly, the FDA's letter made clear that the agency was phasing out its use of NDA number 022432, as demonstrated by the FDA's instructions to Questcor to address all submissions "to the original NDA 008372 for this drug product" and to stop using NDA number 022432, A.R. 706 (stating "[i]n the future, do not make submissions to this NDA [022432] except for the final printed labeling"). The FDA's letter also required Questcor to submit a risk evaluation and mitigation strategy (REMS) and directed the company to identify the submission as an "NDA 008372 REMS Assessment," "New Supplement for NDA 008372," and "New Supplement (New Indication for Use) for NDA 008372." A.R. 705 (formatting omitted).

In early 2011, Questcor submitted the required final printed labeling under NDA number 022432 and then submitted an application—referred to as a "Changes Being Effected Labeling Supplement"—to revise the labeling for NDA number 008372. A.R. 700. Questcor explained that it was requesting the labeling revision to NDA number 008372 "[i]n order for the approval of the indication for the Treatment of Infantile Spasms to be associated with the parent NDA number, 08-372, since the tracking NDA number [022432] *will no longer be used*." A.R. 694 (emphasis added). The application further identified "tracking NDA 22,432" as a "Supplemental NDA for Treatment of Infantile Spasms" and "efficacy supplement." A.R. 700. The FDA approved the labeling revision nearly four years later on March 24, 2015 and, once again, reiterated that "the tracking NDA number 022432 will no longer be used." A.R. 688.

II. QUESTCOR SEEKS TO RESET THE BASE DATE AMP FOR ACTHAR

About three months after the FDA first rejected Questcor's initial efficacy supplement in 2007, Questcor raised Acthar's price from $1,650 to $23,269 per vial. A.R. 144, 636. Despite this price hike, however, Questcor grew antsy several years later about what it perceived to be the drug's curtailed profitability under the Medicaid Drug Rebate Program, as demonstrated by a letter Questcor's General Counsel[10] sent to CMS on May 8, 2012. *See* A.R. 141, 145.

Questcor's letter sought to reset Acthar's base date AMP—and thereby lower the company's Medicaid rebate liability—based on what Questcor characterized as the "significant revisions to the Acthar label" that were required by the FDA's 2010 approval to add infantile spasms as an indication. A.R. 141–149. Questcor contended that Acthar's rebate liability was greater than its Medicaid revenue and, as a result, the company was losing money by participating in the Medicaid Drug Rebate Program. A.R. 145. Questcor went on to insinuate that Acthar's ongoing participation in the program might be "untenable," A.R. 142, if its rebate liability was not reduced, A.R. 145. Questcor therefore proposed setting a new base date AMP to decrease Acthar's rebate liability,[11] A.R. 141, and "thereby ensure Questcor's continued participation in and payment of rebates under the MDRP [Medicaid Drug Rebate Program]," A.R. 146.

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[10] Questcor's General Counsel at that time also served as a Senior Vice President and Corporate Secretary. A.R. 147.

[11] Questcor's letter seeking a new base date AMP went on to suggest that Questcor's exit from the Medicaid Drug Rebate Program was not "in the interest of CMS, as we believe state Medicaid programs likely still will be required to cover Acthar's use for infantile spasms even if Questcor does exit the program." A.R. 142. According to Questcor, the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit would provide Medicaid coverage "for children who need Acthar even if Questcor withdrew" from the Medicaid Drug Rebate Program. A.R. 142 n.3.

Questcor, through its General Counsel, offered two alternative approaches to implement a new base date AMP and keep Questcor in the Medicaid Drug Rebate Program. A.R. 141–142. Questcor's "preferred" approach was "for CMS to permit the Company to establish a new base date AMP for the *current* Acthar NDC-9 [National Drug Code] [12] for use on a prospective basis upon the issuance of the Covered Outpatient Drug final rule," which Questcor noted was a proposed rule that would allow manufacturers to reset the base date AMP for existing drugs "using the revised definition of AMP included in the Patient Protection and Affordable Care Act of 2010 ('ACA')." A.R. 141–42 (emphasis in original). The second approach would require Questcor to obtain a new National Drug Code based on the "major label revision" required in the FDA's 2010 approval to add infantile spasms as an indication. A.R. 142. Upon receiving the new National Drug Code, Questcor would then "calculate and report a new base date AMP for the product in accordance with MDRP [Medicaid Drug Rebate Program] standards." A.R. 142.

Although Questcor's letter portrayed the FDA approval to add infantile spasms to Acthar's label as a "major label revision," A.R. 142, and a "significant revision . . . in the conditions under which [Acthar] will be marketed and distributed," A.R. 144, at no point did Questcor suggest that Acthar with the infantile spasm indication was an entirely new drug that qualified for a new base date AMP based on the FDA's assignment of NDA number 022432 to

[12] The FDA's National Drug Code Directory website explains that "[d]rug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory[,] which is updated daily." Nat'l Drug Code Directory, U.S. Food & Drug Admin., https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory (last visited July 30, 2019). The National Drug Code consists of digits that identify the labeler, product, and package size and type. *See* 21 C.F.R. § 207.33(a). The FDA assigns the labeler code. 21 C.F.R. § 207.33(b)(1)(i). The drug manufacturer proposes the product and packaging codes. 21 C.F.R. § 207.33(d).

the supplement application approved in 2010. To the contrary, Questcor expressly stated that it was "the FDA's recent expansion and revision of the Acthar label" that "provide Questcor and CMS with the ability to reset the Acthar base date AMP going forward."[13] A.R. 146.

On August 6, 2012, CMS responded to Questcor's request to set a new base date AMP for Acthar. A.R. 148. CMS granted the request but jettisoned Questcor's two proposed approaches. A.R. 148. Instead, CMS indicated that it was granting the request because Acthar with the infantile spasm indication was a new drug product that the FDA had approved under a different NDA "from the original product":

> As noted in your letter, the Food and Drug Administration (FDA) recently approved Acthar Gel for use in treating infantile spasms. It is your position in light of FDA's approval that Acthar is eligible for a new base[] date AMP.
>
> We have reviewed your request and agree that Acthar Gel is eligible for a new base date AMP. 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 [NDA[14]] *from the original product*, Questcor may set a new base date AMP *for this drug*.
>
> . . .
>
> For the purpose of the Medicaid Drug Rebate Program we believe the assignment of a new NDC-9 to the recently approved Acthar Gel would be necessary. We

[13] Indeed, Questcor's outside counsel contacted officials at CMS in January 2012 to request a meeting to discuss whether Acthar was entitled to a new base date AMP in light of the fact that it "recently received FDA approval for a *revised label* for its product H.P. Acthar Gel . . . ." A.R. 648 (emphasis added). And Questcor's letter requesting to change Acthar's base date AMP contained a footnote stating that "Questcor believes that the FDA's *changes to the Acthar label, including the addition of the infantile spasms indication*, qualify the drug for a new product code or NDC-9." A.R. 77 n.10 (emphasis added).

[14] CMS's response inadvertently referred to a National Drug Code (NDC) rather than New Drug Application (NDA), *see* A.R. 148, but that error was later corrected in a letter dated September 19, 2012, which stated that "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," A.R. 169.

> understand Questcor's concerns regarding how this option might create some confusion; however, the Centers for Medicare & Medicaid Services (CMS) does not have the current capability to allow a manufacturer to replace the original reported base date AMP with a new base date AMP *midway through the life of a product*.

A.R. 617 (emphases added). Accordingly, CMS authorized Questcor to set a new base date AMP for Acthar based on the now defunct NDA number 022432, but directed Questcor to secure a new National Drug Code for the drug. A.R. 148–49. At that time, Acthar's National Drug Code was 63004-7731-01. *See* A.R. 151 (identifying the "original NDC 63004-7731-01"). Questcor obtained a new National Drug Code for Acthar in 2013, which was 63004-8710-01. A.R. 30, 54, 137.

III. CMS DISCOVERS THAT NDA NUMBER 002432 WAS RENDERED OBSOLETE UPON APPROVAL AND THE LABEL REVISION AUTHORIZING QUESTCOR TO MARKET ACTHAR FOR INFANTILE SPASMS WAS CONSOLIDATED UNDER NDA NUMBER 008372

Over the next several years, it became apparent that CMS might have been misguided in its decision to allow Questcor to reset Acthar's base date AMP based on the fact that Questcor's efficacy supplement application was provisionally assigned a different NDA number. First, the FDA's October 15, 2010 letter approving Questcor's application to revise Acthar's label to include infantile spasms as an indication expressly stated that Questcor should use NDA number 008372 and not NDA number 002432 for all future submissions. A.R. 312. Although Questcor arguably alluded to this fact in a footnote to its May 2012 letter requesting to change Acthar's base date AMP, *see* A.R. 74 n.4, that footnote did not make clear that, with the exception of Questcor's submission of final carton and container labels,[15] NDA number 002432 became

[15] The FDA's October 15, 2010 approval letter directed Questcor to submit final carton and container labels and designate the submission as "for approved NDA 022432." A.R. 309. The letter mandated, however, that all "other submissions should be addressed to the original NDA 008372 for this drug product, not to this NDA." A.R. 312.

obsolete upon approval. *See* A.R. 74 n.4 (stating that "Acthar's original NDA is number 08-372, and the FDA has informed Questcor that the agency intends to revise its record so that the approval for infantile spasms is reflected as part of the product's original NDA, No. 08-372" but "[t]hat has not yet occurred").

In addition, a private research analyst contacted CMS by email on September 6, 2012—only a month after CMS approved Questor's request to lower Acthar's base date AMP—and questioned CMS's rationale for authorizing Questcor to reset Acthar's base date AMP based on the provisional NDA number given that the drug had not otherwise changed. *See* A.R. 170–72. The analyst stated that she was "trying to understand the circumstances under which Medicaid would pay *MORE* for this drug that was first approved by FDA in 1952." A.R. 170 (emphasis in original). She then posed several queries, including: "If a type 6 NDA is an administrative change . . . is it really possible that this type of NDA could possibly trigger a 76.9% loss to Medicaid on each Medicaid vial, with a current AWP of more than $34,000?" The analyst commented that "[i]t's hard to imagine that there is any common sense rationale that would permit this." A.R. 172. She also asked whether there was "some other change from sNDA 8372 and NDA 22432 in the drug beyond the wrong FDA reviewing department" and expressed her opinion that "[t]here is no doubt that taxpayer dollars will be wasted." A.R. 172.

About nine months later, on May 28, 2013, a CMS official emailed Questcor's Director of Business Analytics and Evaluation to request that Questcor correct Acthar's base date AMP. A.R. 164. The CMS official observed that Acthar's National Drug Code number was associated with a product that was approved under NDA 008372 and stated that Questcor therefore needed to "follow the baseline data" for Acthar that was historically associated with that NDA number at the time Questcor purchased the drug. A.R. 165. The CMS official directed Questcor to several

numbered agency publications for guidance about a drug product's base date AMP being tied to the NDA number rather than the National Drug Code number. A.R. 165.

Later that same year, an official from the Ohio Department of Medicaid contacted CMS by email to ask why Acthar's National Drug Codes 63004-7731-01 and 63004-8710-01 had different base date AMPs when both products appeared to be the same drug. A.R. 163. A CMS official responded and said that "[t]he new Acthar H.P. NDC is being marketed pursuant to a new NDA, and therefore the product has a different base AMP quarter." A.R. 163.

Another year or two passed before a CMS official emailed the FDA's Center for Drug Evaluation and Research on October 9, 2015 and requested that the Center identify the correct NDA number for Acthar. A.R. 159. The CMS official pointed out that searches for Acthar on the FDA's website drugs@fda.gov resulted in "two different NDA numbers [being] referenced—008372 and 022432." A.R. 159. The CMS official noted that the approval letter associated with NDA number 022432 "indicates that NDA number 022432 will no longer be used." A.R. 159–60. The CMS official then asked whether "that mean[s] tha[t] the only NDA used for the marketing of Acthar HP gel is 008372?" A.R. 160. The CMS official also asked whether "the information referencing NDA 022432 [will] be removed from drugs@fda?" A.R. 160. A Drug Information Specialist from the Center responded and said that he "confirmed that the only active NDA for HP Acthar Gel is 008372" and he was "notifying the Drugs@FDA team about the older NDA"—i.e., NDA number 022432. A.R. 159.

A couple of months later, on November 24, 2015, CMS's Director for the Division of Pharmacy at the Center for Medicaid and CHIP Services contacted the official who signed the FDA's March 24, 2015 letter approving Questcor's "Changes Being Effected" supplemental new drug application—which effectively consolidated under NDA number 008372 the labeling

revision that added infantile spasms to Acthar's indications[16]—to ask when NDA number 022432 became obsolete and the reason for its demise. A.R. 158 ("Is it the date you signed on 3/24/2015, or does this letter invalidate NDA number 022432 altogether since it's first approval back on October 15, 2010?"). A project manager at the Center for Drug Evaluation and Research responded and stated, among other things, that "Type-6 NDAs are administratively closed upon approval." A.R. 157. The project manager further explained that, "[u]pon approval of the infantile spasms efficacy supplement we requested that the sponsor submit a labeling supplement to the parent NDA [008372] for administrative purposes to update the labeling under the parent NDA." A.R. 157.

Two weeks later, on December 8, 2015, the same CMS official who previously alerted the FDA's Center for Drug Evaluation and Research that two different NDA numbers were associated with Acthar on the Drugs@FDA.gov website once again contacted the Center by email to advise that "Drugs@FDA is still showing that the NDA number for HP Acthar Gel is 022432." A.R. 154. The Center responded by confirming that, although both NDA numbers 008372 and 022432 were listed on the website Drugs@FDA.gov, NDA number 022432 was "no longer used." A.R. 154 (bracketing omitted). The Center explained that NDA number 022432 was still appearing on the website because there were ongoing agency deliberations about how to "list" the "Type 6 approvals" on the site.[17] A.R. 154 (stating "I was informed that the policy on

[16] *See* A.R. 30 (acknowledging that the FDA intended to "consolidate NDA 022432 with NDA 008372" and ultimately did consolidate the two applications in 2015).

[17] Mallinckrodt's claim that the "FDA repeatedly refused to answer" CMS's questions about whether Acthar was being marketed under NDA number 008372 versus NDA number 022432 is not credible upon examination. As already discussed, the FDA unequivocally confirmed that: "the only active NDA for HP Acthar Gel is 008372," A.R. 159; Type 6 NDAs like NDA number 022432 "are administratively closed upon approval" and NDA number 008372 was the "parent" of NDA number 022432, A.R. 157; and NDA number 022432 was "no longer used" by the

how to list these Type 6 approvals is still being deliberated" but "[f]eel free to check back in a few months or periodically at the NDA listings for further updates").

IV. CMS DIRECTS QUESTCOR TO CORRECT ITS MEDICAID PROGRAM REPORTING DATA TO REFLECT THAT ACTHAR IS BEING MARKETED UNDER NDA NUMBER 008372

These events culminated in CMS formally notifying Questcor and Mallinckrodt, which had merged, that they were reporting the wrong base date AMP for Acthar. A.R. 151. That notice came in the form of a letter dated April 13, 2016, in which CMS directed the companies to correct the data they had reported in the Medicaid Drug Rebate Program's Drug Data Reporting for Medicaid (DDR) system to reflect that Acthar was being marketed under NDA number 008372—not NDA number 022432:

> 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 is listed as approved under NDA 008372 on FDA Online Label Repository at http://labels.fda.gov/getPackageCode.cfm. 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 FDA approval letter for H.P. Acthar Gel provided by Drugs@FDA at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/022432x000ltr.pd, 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 NDC 63004-8710 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 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.

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agency but was appearing on the Drugs@FDA website simply because the agency had not yet set a policy about how it should "list" NDA Type 6 applications there, A.R. 159.

A.R. 151 (formatting omitted). The letter also advised the companies that the base date AMP associated with Acthar's reported National Drug Code needed to be revised to reflect the base date AMP that applied to NDA number 008372:

> Additionally, as provided in Manufacturer Release No. 90 . . . baseline data of an NDC for a single source drug or innovator multiple source drug must follow the NDA. Therefore, the baseline data of NDC 63004-8710 need to follow the baseline data of the original NDC 63004-7731-01, which includes revision to the base AMP of NDC 63004-8710.

A.R. 151.

What ensued over the course of the next three years were a series of communications—via emails, letters, and meetings—between Mallinckrodt officials and CMS officials, all of whom asserted and reasserted their respective, albeit opposing, positions about whether Acthar was entitled to a new base date AMP consistent with CMS's 2012 determination. A.R. 12–150. Whether intentional or not, a July 6, 2016 email from Mallinckrodt to CMS made the inexact statement that NDA number 022432 involved the FDA's "approval" of "the product that was discussed in the CMS letter of August 6, 2012." A.R. 83. CMS was not misled, however, and responded by email on March 20, 2017 to explain that:

> [I]t 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.

A.R. 81. Throughout these communications, Mallinckrodt appears to have believed that it was engaged in negotiations with CMS,[18] whereas CMS remained resolute and, on March 12, 2019, sent Mallinckrodt a letter stating that, "[a]s 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." A.R. 13. CMS maintained that, "[b]ecause 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.R. 13.

CMS effectively shut down any further discussions between the parties via a March 27, 2019 email that HHS's General Counsel sent to Mallinckrodt's General Counsel and the company's outside counsel. A.R. 11. The email canceled a planned meeting between the parties in light of the HHS General Counsel's conclusion that CMS's April 13, 2016 letter to Questcor was the agency's final decision. *See* A.R. 11 ("I've reviewed the underlying documents and have concluded that the April 13, 2016 letter from CMS to Mallinckrodt constituted CMS' final decision on the relevant issue. Therefore . . . any meeting . . . would not and could not be productive.").

Mallinckrodt nevertheless took one last run at CMS's position in an April 12, 2019 letter in which Mallinckrodt's General Counsel sought "to engage with [CMS] to discuss a potential middle ground where Mallinckrodt would agree to a pathway for implementing Acthar's pre-

[18] *See* Mallinckrodt's Mot. for Prelim. Inj. Br. 19 (stating that "[a]lthough Mallinckrodt has continued to seek further dialogue with the agency since then, those efforts have been rebuffed").

2013 base date AMP on a prospective basis only." A.R. 9. Mallinckrodt's General Counsel proposed that CMS "acknowledge that, under its interpretation of the law to date, Mallinckrodt's use of Acthar's post-2012 base date AMP was appropriate, but would take appropriate steps to change its interpretation of the law, on a prospective basis, such that, going forward, Acthar's pre-2013 base date AMP would be implemented." A.R. 9. CMS declined to consider Mallinckrodt's proposal and, instead, reaffirmed that its "position remains the same, as reflected in [the HHS General Counsel's] March 27, 2019 email . . . ." A.R. 4.

CMS cemented its position on May 10, 2019 by sending Mallinckrodt a letter notifying the company that it must correct the information in the Drug Data Reporting Medicaid system in 14 days or risk having its National Drug Codes flagged as "out of compliance" in the system. A.R. 2. CMS added that it "may also 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." A.R. 2. CMS now characterizes this letter as the agency's final decision, *see* Gov't's Reply Br. 15 (stating that "the relevant date for purposes of final agency action is May 2019 when the agency threatened to find Mallinckrodt out of compliance in the drug data reporting system"), which Mallinckrodt has not disputed in its legal briefs or during oral arguments.

Ten days after receiving CMS's final decision, Mallinckrodt filed this lawsuit. *See* Verified Compl., ECF No. 1. Mallinckrodt then immediately moved for a preliminary injunction to enjoin the government from "suspending Mallinckrodt's participation in the Medicaid Drug Rebate Program and/or taking any other action as a result of a recent determination by the Centers for Medicare & Medicaid Services (CMS) regarding the base date average manufacturing price (AMP) for Mallinckrodt's drug product Acthar Gel® (repository

corticotropin) injection (Acthar)." Mallinckrodt's Mot. for Prelim. Inj. 1, ECF No. 4. During a teleconference that took place on May 24, 2019, however, the then-presiding judge secured the parties' agreement to consolidate the issues raised in Mallinckrodt's preliminary injunction motion with a decision on the merits of summary judgment motions. *See* Teleconference Tr. 5–9, May 24, 2019, ECF No. 9.

Mallinckrodt's Verified Complaint alleges two claims. Mallinckrodt's first claim is that CMS's (1) 2016 determination that Acthar was not a distinct single source drug entitled to establish a new base date AMP, (2) ambition to recover the underpaid rebates from Mallinckrodt, and (3) indication that it might take enforcement action against Mallinckrodt were all unlawful, arbitrary, and capricious under the Administrative Procedure Act (APA), 5 U.S.C. §§ 700–706. Verified Compl. ¶¶ 94–106 (Count I). Mallinckrodt's second claim is that it relied on CMS's 2010 authorization granting Questcor approval to establish a new base date AMP and CMS's subsequent "failure to give Mallinckrodt advance notice of its newfound interpretation of 'single source drug' violates basic principles of fair notice." Verified Compl. ¶ 110 (Count II). Mallinckrodt also takes issue with CMS's "effort to seek enforcement action," which Mallinckrodt asserts "violates the procedural due process guarantees of the Fifth Amendment to the United States Constitution and the APA." Verified Compl. ¶ 111 (Count III). At stake are potentially hundreds of millions of dollars in retroactive rebate adjustments dating back to 2013 that Mallinckrodt will owe Medicaid agencies. *See* Mallinckrodt's Prelim. Inj. Br. 2, ECF No. 4-1 (arguing that if Mallinckrodt is forced to correct Acthar's base date AMP in the Drug Data Reporting for Medicaid (DDR) system, "[i]t would automatically trigger adjustments to the Acthar rebate calculations—not just prospectively, but *retroactively*, all the way back to 2013,

resulting in losses totaling in the hundreds of millions of dollars for Mallinckrodt" (emphasis in original)).

LEGAL STANDARDS

I. PRELIMINARY INJUNCTIONS

Preliminary injunctions are "extraordinary" remedies that are awarded "only . . . upon a clear showing that the plaintiff is entitled to such relief." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 10 (D.C. Cir. 2019) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008)), *cert. denied*, No. 19-296, 2020 WL 981797 (U.S. Mar. 2, 2020). To make this showing the plaintiff bears the burden of persuading the court that (1) the plaintiff is likely to succeed on the merits, (2) the plaintiff is likely to suffer irreparable harm if there is no preliminary relief, (3) the balance of equities favor the plaintiff, and (4) it is in the public interest to grant a preliminary injunction. *Id.* If, however, the plaintiff fails to establish the first factor—a likelihood of success on the merits—the court "need not proceed to review the other three preliminary injunction factors." *Arkansas Dairy Co-op Ass'n v. U.S. Dep't of Agric.*, 573 F.3d 815, 832 (D.C. Cir. 2009).

II. SUMMARY JUDGMENT

Rule 56 of the Federal Rules of Civil Procedure mandates that a federal court grant summary judgment in favor of a moving party when there are no genuine disputes about material facts and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A dispute is genuine if "a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if it "might affect the outcome of the suit under the governing law." *Id.*

The party moving for summary judgment bears the burden of showing that there are no genuine disputes about material facts. *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970). To determine whether a dispute about a material fact is genuine, the Court must view the evidence in the light that is most favorable to the party opposing the motion and draw all reasonable inferences in that party's favor. *Tolan v. Cotton*, 572 U.S. 650, 651, 656 (2014) (per curiam). The Court may not weigh the evidence or make credibility determinations. *Allen v. Johnson*, 795 F.3d 34, 38 (D.C. Cir. 2015).

To successfully oppose a motion for summary judgment, the nonmoving party must offer sufficient evidence of a factual dispute—not mere allegations—such that a jury or judge is necessary "to resolve the parties' differing versions of the truth at trial." *First Nat. Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968). Although the evidence need not be "in a *form* that would be admissible at trial, the evidence still must be capable of being converted into admissible evidence." *Gilmore v. Palestinian Interim Self-Gov't Auth.*, 843 F.3d 958, 969 (D.C. Cir. 2016) (emphasis in original) (quoting *Gleklen v. Democratic Cong. Campaign Comm., Inc.*, 199 F.3d 1365, 1369 (D.C. Cir. 2000)). "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson*, 477 U.S. at 247–48 (emphases in original).

III. APA REVIEW

The standard of review for summary judgment under the APA requires the Court to hold unlawful and set aside agency action, findings, and conclusions that the Court finds to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *AstraZeneca Pharm. LP v. Food & Drug Admin.*, 713 F.3d 1134, 1139 (D.C. Cir. 2013); 5

U.S.C. § 706(2)(A). An agency action is arbitrary and capricious when the agency "entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise[.]" *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *Gresham v. Azar*, No. 19-5094, 2020 WL 741278, at *4, ___ F.3d ___ (D.C. Cir. Feb. 14, 2020).

To be sure, the scope of arbitrary and capricious review is narrow, *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019), and "highly deferential," *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 162 (D.C. Cir. 2003). The Court's role is to "determine only whether the [agency] examined 'the relevant data' and articulated 'a satisfactory explanation' for [its] decision, 'including a rational connection between the facts found and the choice made.'" *Id.* (quoting *Motor Vehicle Mfrs. Assn. of U.S., Inc.*, 463 U.S. at 43). It is well established that a court may not substitute its own judgment for that of federal agencies and "may not supply a reasoned basis for the agency's action that the agency itself has not given." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974). It is also well established, however, that an agency's decision need not "be a model of analytic precision to survive a challenge." *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1404 (D.C. Cir. 1995). Courts will "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp.,* 419 U.S. at 286.

The APA mandates that courts must "review the whole record or those parts cited by a party" when reviewing an agency's action. 5 U.S.C. § 706. The Court's review is therefore confined to the Administrative Record, which "includes all materials compiled by the agency that were before the agency at the time the decision was made." *James Madison Ltd. by Hecht v.*

Ludwig, 82 F.3d 1085, 1095 (D.C. Cir. 1996) (internal citations and quotation marks omitted). "[T]he function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 769 (9th Cir. 1985). The Court will not consider post hoc agency rationalizations that the Administrative Record does not support. *See Caiola v. Carroll*, 851 F.2d 395, 400 (D.C. Cir. 1988).

ANALYSIS

Mallinckrodt contends that CMS correctly decided in 2012 that Acthar was eligible for a new base date AMP after the FDA approved Questcor's efficacy supplement application to revise the drug's label by adding infantile spasms as a new indication. The gist of Mallinckrodt's argument is this: When the FDA approved Questcor's efficacy supplement application to add infantile spasms as an indication after converting it into a Type 6 "new drug application" and assigning it a new (albeit now defunct[19]) NDA number—022432—the result was a "new drug application" approved by the FDA. And, because Questcor and Mallinckrodt thereafter began producing and distributing Acthar using that NDA number, Acthar with the infantile spasm indication satisfied the statute's definition of a "single source drug" eligible for a new base date AMP because it was a "drug" that was being "produced and distributed" under a "new drug application" approved by the FDA. *See* Mallinckrodt's Prelim. Inj. Br. 20–28; Mallinckrodt's Summ. J. Br. 4–7, ECF No. 22-1. Mallinckrodt therefore challenges CMS's later decision requiring the manufacturer to correct its reporting and apply the base date AMP associated with Acthar's FDA approval under NDA number 008372. *Id.* Mallinckrodt argues

[19] An FDA letter dated March 24, 2015 and addressed to Questcor states that "tracking NDA number 022432 will no longer be used." A.R. 688–690.

that CMS's change of heart was unlawful, arbitrary, and capricious for three reasons: (1) the agency's determination that Acthar is not a distinct single source drug is contrary to the terms of the statutory Medicaid Drug Rebate Program; (2) the agency's decision violates CMS's own regulations; and (3) CMS failed to explain why its position changed. Mallinckrodt's Prelim. Inj. Br. 21–29. Mallinckrodt also separately claims that CMS's decision violates principles of fair notice and will be impermissibly retroactive. *Id.* at 29–36.

CMS resists Mallinckrodt's challenge by pointing out that the agency's 2012 decision allowing Questcor to set a new base date AMP for Acthar was based on facts Questcor presented that "showed that the U.S. Food and Drug Administration . . . recently had approved Acthar as an entirely new drug" versus simply approving a label revision to add an indication for infantile spasms. Gov't's Opp'n Br. 1, ECF No. 18 (Sealed). CMS interprets the Medicaid Drug Rebate Program statute as "set[ting] the base date AMP for each dosage form and strength of a single source drug, such as Acthar, by reference to the FDA's approval of an NDA under which the drug is marketed." Gov't's Opp'n Br. 17–18. According to CMS, "[c]hanges to an existing product result in a new base date AMP only if those changes result in a new drug being marketed under a new NDA or the changes are to dosage form or strength." *Id.* at 18. CMS concludes that, regardless of whether the FDA assigned a provisional NDA number to Questcor's efficacy supplement application to revise Acthar's label by adding infantile spasms as an indication, the FDA's approval of that application "did not create a new drug" because "the drug's composition remained the same and the drug has been marketed only under the original FDA approval from 1952, NDA 008372." *Id.* And once CMS became aware that NDA number 022432 was obsolete and did not involve a new drug approval, the agency directed both Questcor and Mallinckrodt to correct their drug reporting for the Medicaid Drug Rebate Program. *Id.* at 26. CMS therefore

defends both its 2012 and 2019 decisions as consistent interpretations of the statute, lawful, adequately explained, and supported by the Administrative Record. *Id.* at 17–23.

I. CMS COMPLIED WITH THE MEDICAID DRUG REBATE PROGRAM STATUTE AND THE ADMINISTRATIVE PROCEDURE ACT

A. CMS Lawfully Determined that the Medicaid Drug Rebate Program Statute Requires that Acthar's Base Date AMP be Calculated Based on the Date When the FDA Approved the Drug Under NDA Number 008372

Turning first to Mallinckrodt's allegation that CMS failed to comply with the Medicaid Drug Rebate Program statute when it reversed its 2012 decision allowing Acthar's base date AMP to be reset, Mallinckrodt asserts that this claim "turns on whether FDA's approval of NDA 022432 entitles Acthar to be treated as a distinct 'single source drug.'" Mallinckrodt's Summ. J. Br. 4. Framed this way, the question for the Court is whether the Medicaid Drug Rebate Program statute contemplates that, if the FDA approves an efficacy supplement application to add a new indication to an existing drug's label after converting that application to a Type 6 NDA and assigning it a different NDA number from the number of the NDA under which the drug received FDA approval for marketing, is that same drug thereby transformed into a new "single source drug" entitled to a new base date AMP. This is a question of statutory interpretation and, although both parties subscribe to the theory that the Medicaid Drug Rebate Program statute is clear and unambiguous, their views about what the statute means diverge.[20]

[20] Mallinckrodt argues that the Court need not give deference to CMS's interpretation of the Medicaid Drug Rebate Program statute pursuant to the Supreme Court's decision in *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984), because the government has forfeited *Chevron's* application by failing to invoke it. Mallinckrodt's Summ. J. Br. 6 n. 3. The Court does not apply *Chevron*, however, when Congress's intent is clear from the statute; rather, in such situations, the Court applies the ordinary tools of statutory interpretation. *Safari Club Int'l v. Zinke*, 878 F.3d 316, 326 (D.C. Cir. 2017). Furthermore, the D.C. Circuit's decision in *Guedes*, 920 F.3d 1, establishes that government counsel cannot waive or forfeit the applicability of *Chevron* deference "unless the underlying agency action fails to manifests its engagement in the kind of interpretive exercise to which review under *Chevron* generally applies—i.e.,

"In the interpretation of statutes, the function of the courts is easily stated. It is to construe the language so as to give effect to the intent of Congress." *United States v. Am. Trucking Ass'ns*, 310 U.S. 534, 542 (1940). To do so, the Court adheres to the "preeminent canon of statutory interpretation" that requires the Court to "'presume that [the] legislature says in a statute what it means and means in a statute what it says there.'" *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004) (quoting *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253–254 (1992)). The Court's analysis therefore "begins with the statutory text, and ends there as well if the text is unambiguous." *Id.* Ultimately, "[a]s in all cases of statutory construction, [the Court's] task is to interpret the words of . . . statutes in light of the purposes Congress sought to serve." *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 608 (1979).

Congress's purpose for enacting the Medicaid Drug Rebate Program was "to further reduce Medicaid spending." *Iowa Dep't of Human Servs. v. Centers for Medicare & Medicaid Servs.*, 576 F.3d 885, 886 (8th Cir. 2009). The program achieves this purpose by mandating that drug manufacturers that seek to have their drugs covered by Medicaid must agree to provide rebates to states to offset the rising costs of those drugs. *See* 42 U.S.C. §§ 1396r-8(a)(1), (b)(1)(B).

42 U.S.C. § 1396r-8(c) is the section of the Medicaid Drug Rebate Program statute that governs how rebates are determined—including a drug's so-called "base date AMP." As already discussed in the section of this decision addressing the statutory and regulatory structure of the case, the relevant provisions in 42 U.S.C. § 1396r-8(c) set forth the rebate amount a drug manufacturer must pay for "each dosage form and strength of a single source drug." 42 U.S.C.

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interpreting a statute it is charged with administering in a manner (and through a process) evincing an exercise of its lawmaking authority." *Id.* at 22 (internal quotation marks omitted).

§ 1396r-8(c)(1)(A). The statute currently defines the phrase "single source drug" to mean in relevant part "a covered outpatient drug . . . which is produced or distributed under a new drug application approved by the Food and Drug Administration." 42 U.S.C. § 1396r-8(k)(7)(iv).

Mallinckrodt seizes on the statute's definition of "single source drug" as the linchpin of its claim that CMS correctly determined in 2012 that Acthar with the infantile spasm indication qualified for a new base date AMP. Mallinckrodt's Mot. for Prelim. Inj. Br. 22–23. Unpacking Mallinckrodt's argument proceeds thusly: NDA number 022432 was, on its face, a "new drug application" that was "approved by the Food and Drug Administration." *Id.* at 22. Acthar with the infantile spasm indication could not be "lawfully marketed" until the FDA approved NDA number 022432. *Id.* After the FDA approved NDA number 022432, Questcor and Mallinckrodt began "producing and distributing" Acthar using that NDA number, including by importing the drug's bulk active ingredient "under" that number.[21] *Id.* at 23. As a result, because Acthar was "produced and distributed" under a "new drug application" (i.e., NDA number 022432) that was "approved by the Food and Drug Administration," *see* A.R. 702, the drug thereby qualified as a distinct "single source drug" that was "eligible for its own base date AMP under the plain meaning of the statute," Mallinckrodt's Mot. for Prelim. Inj. Br. 23.

Mallinckrodt's approach to the statute's interpretation misappropriates the definition of "single source drug" and extrapolates it to mean that a drug's base date AMP may be reset any time the FDA approves an application that has been administratively categorized as an "NDA"—regardless of what action related to a drug was actually occasioned by the approval. Such an

[21] Mallinckrodt never explains what, precisely, it means to "import" Acthar's active ingredient "under" NDA number 022432. All indications, however, suggest that anything Mallinckrodt is doing "under" NDA number 022432 is the product of its own agenda and self-reporting given that the FDA has made clear that number is obsolete for the agency's purposes, A.R. .

interpretation runs counter to the purpose of the Medicaid Drug Rebate Program, however, because it would empower both the agency and drug manufacturers to circumvent Congress's intent to reduce Medicaid spending via drug rebates by simply manipulating how a submitted drug application was administratively categorized. And "[a] statute should ordinarily be read to effectuate its purposes rather than to frustrate them." *Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 719 F.2d at 1165.

Mallinckrodt's urged interpretation also fails to account for the fact that the FDA's 2010 letter approving NDA number 022432 makes clear that the FDA viewed Acthar with the infantile spasm indication to be the same "drug product" that was originally approved in 1952 under NDA 008372. *See* A.R. 706. This is demonstrated by the FDA's statement in the approval letter that "[a]ll . . . submissions should be addressed to the original NDA 008372 *for this drug product*, not to this NDA." A.R. 706 (emphasis added). In other words, the FDA expressly viewed the drug approved under NDA number 008372 and the drug with the label revision adding infantile spasms as an indication that was approved under NDA number 022432 to be one and the same "drug product." A.R. 706.

Moreover, Mallinckrodt's interpretation overlooks the statute's straightforward textual language dictating that a drug's base date AMP is tied to the date when the FDA approved *the drug* and the drug was *first marketed*—not when the FDA approved any so-titled "new drug application" that relates to the drug—although these events might well coincide. The statute provides that the rebate amount for single source drugs consists of the sum of two calculations: (1) the "basic rebate" plus (2) an "additional rebate." 42 U.S.C. §§ 1396r-8(c)(1)(A), (2). The base date AMP only comes into play in the calculation of the "additional rebate." *See* 42 U.S.C. § 1396r-8(c)(2)(A)(ii); *see also* A.R. 1020 (defining "Base Date AMP" in the national Drug

Rebate Agreement to have the meaning set forth in 42 U.S.C. § 1396r-8(c)(2)(A)(ii)(II)). For drugs that were FDA approved on or before October 1, 1990, the statute states that the base date AMP is:

> [T]he average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

42 U.S.C. § 1396r-8(c)(2)(A)(ii)(II). Relevant here, however, the statute further states that if a "covered outpatient drug" is "approved by the FDA" after October 1, 1990 (as would be the case if Acthar with the infantile spasm indication was a new drug), the drug's base date AMP is set based on the "day on which the drug was first marketed":

> 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".[22]

42 U.S.C. § 1396r-8(c)(2)(B).

The plain meaning of this statutory language makes clear that the operative event that determines if and when a drug's base date AMP may be set is the date on which the "covered outpatient drug" was "approved by the Food and Drug Administration." 42 U.S.C. § 1396r-8(c)(2)(B). If a "covered outpatient drug" was "approved by" the FDA after October 1, 1990, as

[22] Legislation enacted after the Medicaid Drug Rebate Program statute appears to refine this calculation based on the dates of the first full calendar quarter that apply but do not otherwise alter the fact that the base date AMP is set based on when the "covered outpatient drug" was "approved by the FDA" and "first marketed." *See, e.g.*, A.R. 983 (discussing the agency's guidance about how to use the correct baseline AMP and Consumer Price Index Urban (CPI-U) factors).

would be the case if Mallinckrodt's theory about Acthar was valid, then the base date AMP must be calculated in accordance with the substitute language found in 42 U.S.C. § 1396r-8(c)(2)(B), which provides that the base date AMP is triggered by the "day on which the drug was first marketed." Aside from the catalyst event of a "covered outpatient drug" being "approved by the FDA," however, the statute does not expressly contemplate any other events that would allow a manufacturer to reset a single source drug's base date AMP during the lifecycle of that drug absent a new formulation, *see* 42 U.S.C. § 1396r-8(c)(2)(C) (providing for the calculation of a base date AMP for new formulations of a single source drug), or, as the government correctly noted, a new dosage form and strength, Gov't's Summ. J. Br. 18 (arguing that "[c]hanges to an existing product result in a new base date AMP only if those changes result in a new drug being marketed under a new NDA or the changes are to dosage form or strength").

The Administrative Record confirms that CMS's 2012 decision allowing Questcor to reset Acthar's base date AMP was premised on the agency's assumption that, because the infantile spasm indication "was approved under a different [NDA] *from the original product*," that meant that Acthar with the infantile spasm indication must be a different "product" from the "original product." A.R. 617 (emphasis added). CMS put Questcor on notice that the agency was relying on this assumption by stating that the agency "does not have the current ability to allow a manufacturer to replace the original reported base date AMP with a new base date AMP *midway through the life of a product*." A.R. 617 (emphasis added). The only possible takeaway from this statement was that CMS believed that Acthar with the infantile spasm indication was an entirely new drug product. Given Mallinckrodt's concession that CMS's rationale was a departure from the two approaches that Questcor's General Counsel had identified and proposed when he advocated for a new base date AMP, *see* Mallinckrodt's Summ. J. Br. 2 (arguing that

"[w]e know that CMS rejected both of Questcor's suggested legal pathways for a new base date AMP and reached its own, unprompted conclusion"), and given that Questcor (and Mallinckrodt) knew all along that NDA number 022432, although titled a "new drug application," was in fact an efficacy supplement to NDA number 008372 that sought the FDA's approval to revise Acthar's label to add infantile spasms as an indication, *see id.* at 3 (challenging CMS's claim that it was ignorant of the fact that Acthar was not "an entirely new drug" on the ground that this claim was "not right" because "Questcor repeatedly told the agency that the drug was first approved in 1952 and received a new indication for infantile spasms in 2010"), 12 (arguing that that "the administrative record makes clear" that the 2010 FDA approval authorizing Questcor to add infantile spasms to Acthar's label "was not [an approval] of an 'entirely new drug' but simply added IS to the labeling"), it would have behooved the companies to clarify the agency's understanding, if only to insulate them from a dispute down the road, as has now come to pass.

Mallinckrodt cites record documents numbered A.R. 621, 622, and 632 as evidence that it clearly disclosed to CMS that Acthar with the infantile spasm indication was not "an entirely new drug." Mallinckrodt's Summ. J. Br. 3. This argument is unavailing upon inspection. Both A.R. 621 and A.R. 622 are pages from Questcor's May 8, 2012 letter requesting to set a new base date AMP for Acthar. A.R. 621 reflects that Questcor told CMS the following:

> The FDA granted Acthar an orphan drug designation for IS in 2003 and approved Acthar under NDA 22-432 for treatment of infantile spasms[4] on October 15, 2010. We believe that prior owners of Acthar did not pursue an approval with FDA based on their view that the economics of obtaining the approval were too burdensome.

A.R. 621. Footnote 4 on that same page stated:

> 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, 08-372. That has not yet occurred.

A.R. 621 n.4. On the next page, Questcor stated:

> Acthar was initially approved for multiple indications in 1952, under NDA 08-372, and then in 1978, an NDA supplement was approved for the use of Acthar to treat multiple sclerosis exacerbations. On October 15, 2010, Acthar was approved to treat infantile spasms under NDA 22-432. The FDA's approval of Acthar for this indication reflects the agency's conclusion, based on data supplied by Questcor, that the product is safe and effective for that use. Upon this approval, however, the FDA also significantly revised Acthar's label and required the implementation [of] a Risk Evaluation and Mitigation Strategy ("REMS"), which the agency determined was necessary for the product's safe use. These changes represent a significant revision in the product's labeling and in the conditions under which it will be marketed and distributed.

A.R. 622. Lastly, A.R. 632 consists of a chart titled "History of Acthar" that states in relevant part "2010 IS Approval Label Modernized."

The Court does not share Mallinckrodt's confidence that these statements alerted CMS to the fact that Acthar with the infantile spasm indication was not a new drug, particularly in light of the way the 1978 approval to add multiple sclerosis as an indication was identified as an "NDA supplement" to NDA number 008372. A.R. 622. In contrast, the statements addressing the approval of NDA number 022432, which was also technically a supplement to NDA number 008372, *see, e.g.*, A.R. 157 (stating that NDA number 022432 "was created for administrative purposes when the sponsor submitted an efficacy supplement for the treatment of infantile spasms), 869 (characterizing Questcor's NDA number 022432 as a "resubmission to your supplemental new drug application for H.P. Acthar® Gel"), discusses the FDA's review of the safety and effectiveness of Acthar for infantile spasm treatment and thereby made the approval under that NDA number appear to involve something more than a label revision to add a new indication. In addition, an email that Mallinckrodt sent to CMS on July 6, 2016 characterized the FDA approval of NDA number 022432 as approving "the product" that was "discussed in the CMS letter of August 6, 2012," thereby suggesting that the FDA approval was for a new drug product rather than a label revision. A.R. 83.

Furthermore, the statements Mallinckrodt cites were made in documents CMS had *before* it issued the August 6, 2012 letter approving a new base date AMP for Acthar, which, as discussed, makes clear that CMS viewed Acthar with the infantile spasm treatment to be a new drug product. *See* A.R. 617. It therefore should have been obvious to Questcor that, however clearly the company thought it had been that Acthar with the infantile spasm indication was not "an entirely new drug," Mallinckrodt's Summ. J. Br. 3, that clarity had bypassed CMS, *see* A.R. 617. It was also apparent that CMS erroneously assumed that the FDA's approval of an NDA that was assigned a different NDA number signaled that the approval was for a new drug product. Placed on notice of that erroneous assumption via CMS's 2012 approval letter, Questcor (and later Mallinckrodt) gambled by implementing a new base date AMP for Acthar without first clarifying this point, particularly in light of the statute's clear language stating that the base date AMP for a single source drug depends on when the "covered outpatient drug" was "approved by" the FDA and, if that approval was after October 1, 1990, the base date AMP is triggered by the date that covered outpatient drug was "first marketed," 42 U.S.C. §§ 1396r-8(c)(2)(A)(ii)(II), (B). Nowhere in the Medicaid Drug Rebate Program statute does it provide for a single source drug's base date AMP to be reset based solely on the FDA approving a so-titled "New Drug Application" that does something other than "approve" a "covered outpatient drug," as occurred here. *See* 42 U.S.C. §§ 1396r-8(c)(2).

The upshot is that CMS correctly assessed in its 2012 approval letter to Questcor that § 1396r-8(c)(2)(A) of the Medicaid Drug Rebate Program statute (cited by reference to § 1927 of the Social Security Act) establishes when a drug's base date AMP attaches. A.R. 617. CMS repeated that correct assessment five years later in a March 20, 2017 email to Mallinckrodt. A.R. 81. CMS also correctly assessed that the base date AMP attaches to a drug in relation to when

the drug was approved by the FDA and the agency lacked authority to change a drug's base date AMP during that drug's lifecycle. A.R. 617 (stating that the base date AMP applies to "each single source or innovator multiple source drug approved by the FDA before or after October 1, 1990" and that CMS lacked authority to "replace the original . . . base date AMP with a new base date AMP midway through the life of a product").

The Court stated at the beginning of this discussion that the legal question was whether the Medicaid Drug Rebate Program statute contemplates that when the FDA approves an efficacy supplement application to add a new indication to an existing drug's label that drug is then entitled to a new base date AMP. As framed specifically with respect to this case, the question is whether Acthar with the infantile spasm indication became a distinct single source drug entitled to a new base date AMP by virtue of the FDA approving Questcor's efficacy supplement application after converting it into a Type 6 NDA and assigning it NDA number 022432. The Court answers that legal question in the negative because the plain language of the statute provides that a single source drug's base date AMP is set based on when the "covered outpatient drug" was "approved by the FDA" and, if approved after October 1, 1990, when that "covered outpatient drug" was "first marketed." 42 U.S.C. §§ 1396r-8(c)(2)(A)(ii)(II), (B). Mallinckrodt and Questcor cannot avoid application of the base date AMP that attached when Acthar was approved by the FDA under NDA number 008372 by manufacturing the existence of a distinct "single source drug" through their own self-interested actions in continuing to use NDA number 022432 despite the FDA's direction otherwise, *see* A.R. 706, and notwithstanding Questcor's own contemporaneous acknowledgment that NDA number 022432 was a "tracking number" that would "no longer be used," A.R. 694.

It is to no avail whether Mallinckrodt continued to produce and distribute Acthar using defunct NDA number 022432 because, regardless of whether the Medicaid Drug Rebate Program statute's definition of "single source drug" could be interpreted in the crafted way that Mallinckrodt advocates, the statute nonetheless makes clear that the base date AMP is triggered by the dates on which the "covered outpatient drug" was "approved by" the FDA and "first marketed"—and it remains undisputed that the date when Acthar was "approved by" the FDA was 1952 when the FDA approved NDA number 008372. *See* Mallinckrodt's Summ. J. Br. 12 (conceding that "the 2010 approval was not of an 'entirely new drug' but simply added IS to the labeling"). Because Acthar was first marketed well before October 1, 1990, its base date AMP under the statute is "the average manufacturer price for . . . the calendar quarter beginning July 1, 1990 . . . 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." 42 U.S.C. § 1396r-8(c)(2)(ii)(II). As a result, CMS's decision requiring Mallinckrodt and Questcor to correct their Medicaid Drug Rebate Program reporting for Acthar to reflect this base date AMP, which was triggered by the FDA's approval of NDA number 008372, was consistent with the statute and not arbitrary, capricious, or an abuse of discretion. For these same reasons CMS's decision also complied with its agency regulations.[23]

[23] Mallinckrodt argues that CMS's decision violated its own agency regulations because those "regulations make clear that a 'single source drug' is '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." Mallinckrodt's Summ. J. Br. 9. This argument does not further Mallinckrodt's case, though, in light of the clear statutory language the Court has already discussed that ties a drug's base date AMP to the date when that drug was approved by the FDA and first marketed.

B. CMS Adequately Explained Why Acthar's Base Date AMP Must Follow the FDA's Approval of NDA Number 008372

Mallinckrodt also protests that CMS's decision requiring the company to correct Acthar's base date AMP to reflect the base date AMP associated with NDA number 008372 was arbitrary, capricious, and unreasonable because the agency vacillated about its rationale for the decision and never actually explained it. Mallinckrodt's Summ. J. Br. 11–17. The Administrative Record, however, demonstrates otherwise.

To reiterate, from the very outset CMS made clear that it was approving a new base date AMP for Acthar because the agency believed that NDA number 022432 involved the FDA's approval of a new drug product to treat infantile spasms. A.R. 169 (stating that CMS was approving a new base date AMP because "[a]s noted in [Questcor's] 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"), 617 (stating that, in accordance with the Medicaid Drug Rebate Program statute, "the base date AMP is calculated based on the new drug application which is approved by the FDA" and "given that the recently approved Acthar Gel was approved under a different [NDA] *from the original product*, Questcor may set a new base date AMP for *this drug*" (emphases added)). That CMS believed NDA number 022432 involved a different "drug product" from the drug approved under NDA number 008372 is substantiated by CMS's statement in its 2012 approval letter that the agency "does not have the current capability to allow a manufacturer to replace the original reported base date AMP with a new base date AMP *midway through the life of a product*." A.R. 617 (emphasis added).

After CMS verified that NDA number 022432 was defunct and did not involve the approval of a new drug, the agency properly directed both Mallinckrodt and Questcor to correct how they were reporting the drug's base date AMP for the Medicaid Drug Rebate Program. *See*

A.R. 2 (referring to the agency's March 12, 2019 letter (A.R. 13) and directing Mallinckrodt to report the appropriate base date AMP for Acthar), 13 (stating that "[b]ecause H.P. Acthar gel [sic] 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"), 81 (noting that "FDA has informed us that type-6 NDAs are administratively closed upon approval," "the administratively assigned NDA 022432 . . . was only for the purpose of FDA approval of the new indication, but not for the approval and marketing of the drug itself," and "the approval of NDA 022432 in 2010 was not for approval of a new drug"), 84 (stating that the "baseline data of a purchased product should be the same as the baseline data of a product marketed previously under the same NDA"), 88 (instructing Questcor and Mallinckrodt that the "baseline data of an NDC for a single source drug . . . must follow the NDA"), 89 (stating that "although the NDA for the use of H.P. Acthar Gel for infantile spasms was initially assigned number 022432" the FDA's approval letter stated that "any future submissions 'should be addressed to the original NDA 008372 for this drug product'"), 106 ("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."), 115 ("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."), 154 (stating that NDA number 022432 was "no longer used").

Thereafter, CMS consistently directed the manufacturers to calculate Acthar's Medicaid rebates using the base date AMP associated with the NDA under which Acthar was approved by the FDA for marketing, which was NDA number 008372. A.R. 2, 13, 81, 106, 115, 133. This direction was compliant with the clear provisos set forth in the Medicaid Drug Rebate Program statute that tether the base date AMP to the date when a "covered outpatient drug" is "approved by" the FDA and, if approved after October 1, 1990, when that "covered outpatient drug" was "first marketed." 42 U.S.C. §§ 1396r-8(c)(2)(A)(ii)(II), (B). However phrased, CMS's message was always the same—(1) the statute requires a single source drug's base date AMP to be set based on the when the FDA approved the drug for marketing, (2) the agency lacked authority to change a drug's base date AMP midway through the life of the drug, and (3) with respect to Acthar, the FDA approved the drug for marketing pursuant to NDA number 008372, not defunct NDA number 022432, which was an efficacy supplement application seeking to revise Acthar's label to add a new treatment indication. A.R. 13, 81, 88, 115. Thus, CMS never wavered from the Medicaid Drug Rebate Program statute's plain language and, contrary to Mallinckrodt's insistence that CMS unfairly and unlawfully changed its position, the record demonstrates that simply was not so. And the path CMS took to reach its decision requiring Questcor and Mallinckrodt to correct the way they were reporting Acthar's base date AMP can be readily and reasonably be discerned. *See Bowman Transp.,* 419 U.S. at 286.

II. CMS COMPLIED WITH THE STATUTE AND DID NOT VIOLATE PRINCIPLES OF FAIR NOTICE OR RETROACTIVE APPLICATION WHEN IT DIRECTED MALLINCKRODT TO CORRECT ACTHAR'S BASE DATE AMP

Mallinckrodt advances two final arguments. The first is that CMS failed to give Mallinckrodt fair notice that the agency's interpretation of the Medicaid Drug Rebate Program statute had changed after it approved Questcor's request to establish a new base date for Acthar

based on the FDA's approval of defunct NDA number 022432. Mallinckrodt's Summ. J. Br. 17–21. Mallinckrodt's second argument is that CMS's decision requiring Mallinckrodt to correct Acthar's base date AMP and face the retroactive rebate payments and possible penalties that would result is "impermissibly retroactive." *Id.* at 22.

A. CMS's 2012 Approval Letter, Pre-Enforcement Efforts, and the Medicaid Drug Rebate Program Statute Supplied Fair Notice that a Single Source Drug's Base Date AMP is Tethered to the Date the Drug was Approved by the FDA and First Marketed

Addressing Mallinckrodt's fair notice argument first, Mallinckrodt is correct that the requirement that federal agencies provide "fair notice" of their regulatory interpretations "has now been thoroughly incorporated into administrative law." *Gen. Elec. Co. v. U.S. E.P.A.*, 53 F.3d 1324, 1329 (D.C. Cir. 1995), *as corrected* (June 19, 1995). It is, however, well recognized that "in many cases the agency's pre-enforcement efforts to bring about compliance will provide adequate notice." *Id.* Furthermore, "[i]f, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expects parties to conform, then the agency has fairly notified [that party] of the agency's interpretation." *Id.*

As an initial matter, the doctrine serves to prevent "deference to an agency's interpretation of its own regulations" from "validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires." *Gates & Fox Co. v. Occupational Safety & Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986). It therefore follows that, if the Court is not applying a standard of deference—for example by applying *Chevron*, *see infra* n. 20—because the statute at issue is clear and unambiguous, then the doctrine would not apply. But even if the doctrine does apply, fair notice was supplied by the clarity of the Medicaid Drug

Rebate Program statute, CMS's 2012 approval letter, and the agency's pre-enforcement efforts to bring about compliance.

To establish a lack of fair notice, Mallinckrodt first argues that "CMS made no mention of its current legal position, which is that a drug might in theory be 'marketed' under an NDA that differs from the one under which it was 'approved.'" *Id.* at 11. But that was never CMS's position, at least according to the Administrative Record. As the Court has repeatedly observed, CMS's 2012 letter approving Questcor's request to set a new base date AMP for Acthar indicates that the approval was premised on CMS's erroneous belief that a "drug product" was approved under NDA number 022432 and, moreover, that this approved "drug product" was different from the "drug product" approved under NDA number 008372, A.R. 617.

Another problem with Mallinckrodt's argument is that CMS's 2012 approval letter put Acthar's manufacturers on fair notice that CMS lacked the authority to change a drug product's base date AMP midway through the life of that product. A.R. 617. As a result, Questcor and Mallinckrodt had fair notice that if Acthar with the infantile spasm indication was not an entirely new drug product, CMS could not authorize a new base date AMP for it.

CMS's pre-enforcement efforts to secure Questcor's and Mallinckrodt's compliance with the Medicaid Drug Rebate Program statute by correcting Acthar's base date AMP to reflect that the drug was approved in 1952 under NDA number 008372 also provided the required fair notice. From 2016 through 2019, CMS gave the manufacturers more than ample opportunity to bring its reporting into compliance so it would not continue to accrue rebate underpayments for which it would be liable.

Of course, fair notice was most certainly supplied by the Medicaid Drug Rebate Program statute, which the Court has explained clearly and unambiguously sets a single source drug's

base date AMP based on the date the "covered outpatient drug" was "approved by" the FDA. 42 U.S.C. §§ 1396r-8(c)(2)(A)(ii)(II), (B). Mallinckrodt has never disputed that H.P. Acthar Gel® was approved for marketing when the FDA approved NDA number 008372 in 1952. Setting aside Mallinckrodt's attempt to mold a new drug out of the statutory and regulatory definitions of "single source drug" and the FDA's approval of now defunct NDA number 022432, which by all accounts was actually an efficacy supplement application to revise Acthar's label under NDA number 008372 (and, indeed, the two NDAs were eventually consolidated), the plain language of the statute confirms that there was never a statutory basis to set a new base date AMP for Acthar. To the extent Mallinckrodt views this issue to be an arguable one of statutory interpretation, its proffered interpretation is not only inconsistent with the purpose of the statute, but would actually thwart Congress's intent to minimize the costs of drugs under Medicaid by, as the Court has already noted, empowering the agency and drug manufacturers to avoid the statutory rebates by manipulating how applications involving existing drugs are administratively classified.

B. CMS's Decision Requiring Mallinckrodt to Correct Acthar's Base Date AMP was not a Newly Adopted Rule or Policy to Which Concerns about Retroactivity Apply

Mallinckrodt's final argument is that CMS's decision requiring Questcor and Mallinckrodt to correct Acthar's base date AMP reflects a change in policy that is being improperly applied retroactively. Mallinckrodt's Summ. J. Mot. 20. Mallinckrodt cites *Retail Wholesale & Dep't Store Union v. NLRB*, 466 F.2d 380 (D.C. Cir. 1972) ("*Retail Union*"), and contends that the factors set forth in that case counsel against allowing CMS to retroactively penalize Mallinckrodt based on the agency's new policy. Mallinckrodt's Summ. J. Mot. 22. The principle of retroactivity applies, however, to newly adopted rules and policies. *See Retail Union*, 466 F.2d at 389 (discussing the principle). Here, though, CMS's decision was not the product of a change in policy or a new policy—and the Court has concluded that Mallinckrodt

had fair notice about how CMS was interpreting the Medicaid Drug Rebate Program statute via the agency's 2012 letter authorizing Questcor to establish a new base date AMP, among other indications. Consequently, the retroactivity principle is inapplicable when considered in light of the particular facts of this case.

CONCLUSION

For all the foregoing reasons, the Court will deny Mallinckrodt's Motion for Preliminary Injunction, ECF No. 4, grant the Government's Motion for Summary Judgment, ECF No. 17, and deny Mallinckrodt's Cross Motion for Summary Judgment, ECF No. 22. An appropriate order will be entered in the public docket.

March 13, 2020

Thomas F. Hogan

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Date: 2020.03.13 14:57:26 -04'00'

Thomas F. Hogan
SENIOR UNITED STATES DISTRICT JUDGE