UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IPSEN BIOPHARMACEUTICALS, INC., *Plaintiff*, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*, *Defendants.*	No. 16-cv-2372 (DLF)

MEMORANDUM OPINION

Ipsen Biopharmaceuticals, Inc. (Ipsen) brought this lawsuit in 2016 against the Secretary of Health and Human Services[1] under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (the APA). Ipsen alleges that the Center for Medicare and Medicaid Services (CMS), a sub-agency within the Department of Health and Human Services (HHS), interpreted Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (the Medicaid Act), in a manner that was arbitrary, capricious, or not in accordance with law. Before the Court are Ipsen's Renewed Motion for Summary Judgment, Dkt. 33, and the Secretary's Renewed Cross-Motion for Summary Judgment, Dkt. 34. Because the Court concludes that CMS's interpretation was neither contrary to law nor arbitrary and capricious, the Court will deny Ipsen's Renewed Motion for Summary Judgment and grant the Secretary's Renewed Cross-Motion for Summary Judgment.

[1] Sylvia Burwell was Secretary of Health and Human Services when Ipsen filed its complaint, but Alex M. Azar II has since taken that position and is automatically substituted as the defendant in this case under Rule 25(d) of the Federal Rules of Civil Procedure.

I. BACKGROUND

A. Statutory and Regulatory Framework

This case implicates the relationship between two federal statutes administered by sub-agencies of HHS: the Medicaid Act, which is administered by CMS, and the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the FDCA), which is administered by the Food and Drug Administration (FDA). Ipsen claims that certain provisions of the FDCA render its product a new drug for purposes of calculating its rebate obligations under the Medicaid Act. The relevant statutory and regulatory provisions are as follows.

1. *Medicaid Act*

Congress created Medicaid in 1965 when it added Title XIX to the Social Security Act. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650 (2003). "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). The program operates by providing federal financial assistance to states that reimburse certain medical costs for the needy. *Pharm. Research*, 538 U.S. at 650.

The Medicaid Act sets forth the circumstances under which drug manufacturers may obtain Medicaid coverage for their drug products. Principally, to obtain coverage for any of its drugs, "the manufacturer must have entered into and have in effect a rebate agreement . . . with the Secretary." 42 U.S.C. § 1396r-8(a)(1). Under these rebate agreements, drug manufacturers agree to pay rebates to the states to help the states cover the costs of providing Medicaid coverage for the manufacturer's drugs. *Id.* § 1396r-8(b)(1)(B).

The amount of the rebate that manufacturers must pay is established by statute and contains two components: the basic rebate and the additional rebate. *Id.* § 1396r-8(c)(1), (c)(2).

At issue in this case is the additional rebate. For the type of drug in question, the additional rebate consists of the difference between the average manufacturer price of the drug for that rebate period and the average manufacturer price of the drug, adjusted for inflation, for "the first full calendar quarter after the day on which the drug was first marketed," multiplied by the total number of units of the drug for which the state made payment over the course of a given rebate period. *Id.* § 1396r-8(c)(2)(A), (c)(2)(B). The "average manufacturer price" (AMP) for the "first full calendar quarter" in which the drug is marketed is known as the "base date AMP."

To put that in layman's terms, the additional rebate fully compensates the state for any amount, in excess of the inflation rate, by which the manufacturer increases the price of a drug after it first comes to market. The "base date AMP" is important because it provides the baseline from which a drug manufacturer's price increases, and therefore its rebate obligations to the states, are calculated. A higher "base date AMP" means lower rebate obligations for the manufacturer, because the net increase in the price of the drug is correspondingly lower. To the extent that manufacturers increase the prices of their drugs over time, a later-in-time base date will correspond to a higher "base date AMP," and thus a lower rebate obligation.

Various definitions contained in the Medicaid Act bear on the statutory question at issue here. First, the Medicaid rebate requirement applies independently to each "covered outpatient drug," 42 U.S.C. § 1396r-8(a), and a "covered outpatient drug" is defined, as relevant here, as "a drug . . . which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act," 42 U.S.C. § 1396r-8(k)(2).

Second, the additional rebate provision described above applies specifically to "single source drug[s]" and "innovator multiple source drug[s]." 42 U.S.C. § 1396r-8(c)(2)(A). As

relevant here, the Medicaid Act defines "single source drug" as "a covered outpatient drug . . . which is produced or distributed under a new drug application approved by the Food and Drug Administration," *id.* § 1396r-8(k)(7)(iv), and an "innovator multiple source drug" as "a multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration," *id.* § 1396r-8(k)(7)(ii). The Medicaid Act's implementing regulations further specify that an "innovator multiple source drug" is a "multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA," and 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." 42 C.F.R. § 447.502.

2. *Food, Drug, and Cosmetic Act*

The FDCA sets forth various requirements for the approval of new drugs. 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). It then imposes a general requirement that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." *Id.* § 355(a).[2]

Section 505(b) provides that persons seeking approval of such new drugs "may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a)." *Id.* § 355(b)(1). Any such application must contain various pieces of information specified by

[2] Section 505(j) of the FDCA refers to the process for filing an abbreviated new drug application (aNDA), which applies to generic drugs. *See* 21 U.S.C. § 355(j). Because the drug product at issue here is not generic, the statutory provisions regarding aNDAs are not relevant to this case.

statute, including, for example, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use," "a full list of the articles used as components of such drug," and "a full statement of the composition of such drug." *Id.* § 355(b)(1)(A), (b)(1)(B), (b)(1)(C).

An application submitted under section 505(b)(1) of the FDCA is referred to as a "new drug application" (NDA). 21 C.F.R. § 314.3. The FDCA's implementing regulations provide, in 21 C.F.R. § 314.50, extensive requirements beyond those imposed in the statute itself that the NDA must meet to obtain FDA approval. *See id*. The regulations also define "new drug application" as "the application described under § 314.50, including all amendments and supplements to the application." *Id.* § 314.3.

The implementing regulations establish a separate process that applies when a manufacturer wishes to make "[s]upplements and other changes to an approved NDA." 21 C.F.R. § 314.70. Under that process, "the applicant must notify FDA about each change in each condition established in an approved NDA beyond the variations already provided for in the NDA," and must "describe the change fully." *Id.* § 314.70(a).

Certain "major changes" to an approved NDA require the manufacturer to submit a "supplemental new drug application" (sNDA) and obtain FDA's approval of that sNDA "prior to distribution of the product made using the change." *Id.* § 314.70(b). Those "major changes" are defined as "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* "Major changes" include things like "[c]hanges that may affect drug substance or drug product sterility assurance," *id.* § 314.70(b)(2)(iii), or

"[c]hanges in a drug product container closure system that controls the drug product delivered to a patient," *id.* § 314.70(b)(2)(vi).

"Moderate changes," defined as changes with a "moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product," also require submission of a sNDA. But the manufacturer need only submit the application "at least 30 days prior to distribution," and need not obtain FDA's approval prior to marketing "the drug product made using the change." *Id.* § 314.70(c). "Minor changes" do not require submission of a sNDA at all; the manufacturer need only document them in its next annual report. *Id.* § 314.70(d).

B. Factual Background

Ipsen sells Somatuline Depot (Somatuline), an injectable drug product available in three strengths (60 mg, 90 mg, and 120 mg). Dkt. 1 (Compl.) ¶ 40; Administrative Record (A.R.) 35. Ipsen received FDA approval of its NDA for Somatuline on August 30, 2007. Compl. ¶ 40; *see* A.R. 35. The FDA approved Somatuline for the treatment of acromegaly, a condition involving excessive growth of the hands, feet, and face as a result of excessive growth hormone production during adulthood. A.R. 35; Compl. ¶ 41.

Since 2007, Ipsen has supplemented its NDA for Somatuline 16 times. *See* U.S. Food & Drug Administration, *Drugs@FDA: FDA Approved Drug Products: Somatuline Depot*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022074 (last accessed May 14, 2020) (listing sNDA approval dates for Somatuline). The changes described in these sNDAs range from changes to Somatuline's dosing regimen, to its manufacturing process, to its efficacy for new indications, to its labeling. *See id.*

Two of these sNDAs are at issue in this case. First, on October 28, 2014, the FDA approved a sNDA for Somatuline that "propose[d] changes to the drug substance and drug product manufacturing processes, and to the drug product container closure system, which include[d] addition of a sharps protection system to the syringe to help prevent needle stick injury after use." A.R. 40. The sNDA also proposed changes that would harmonize the syringe dimensions for the three dosage strengths of Somatuline, as well as corresponding changes to the labeling and the healthcare provider instructions for use. *Id.*; Compl. ¶ 44.

Second, on December 16, 2014, the FDA approved another sNDA for Somatuline, this time "for a new indication for the treatment of patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival." A.R. 76. Ipsen claims that it spent $80 million conducting efficacy trials for this new indication. Compl. ¶ 47. Somatuline was the first drug approved by FDA for this indication, which provides a novel therapy for certain cancer patients. *Id.* ¶ 48. FDA granted Ipsen three years of exclusive marketing privileges in light of the clinical data that Ipsen had produced in support of this new indication. *Id.* ¶ 49.

On January 7, 2015, Ipsen sent CMS a letter indicating its intent to establish an independent base date AMP for purposes of its Medicaid rebate obligations. A.R. 1. Ipsen's letter informed CMS that Ipsen was "poised to launch" a new drug product, in three strengths, that it planned to call Somatuline Depot with Enhanced Device (Somatuline ED), and argued that the three strengths of Somatuline ED "should be considered 'new products' entitled to baseline AMPs separate and distinct from those" of the original Somatuline drug. *Id.*

In support of this argument, Ipsen explained that "Somatuline ED has two separate FDA approvals (supplemental NDAs) distinct from the NDA under which Somatuline [Depot] came to

market (one for the new device and a second for the new indication)." A.R. 3. Ipsen noted that "[t]hese supplemental applications required independent investment, analysis and approval of the delivery mechanism and of the additional indication as well as other changes to the original product." *Id.* Finally, the letter informed CMS that Ipsen intended to begin calculating its Medicaid rebate obligations for Somatuline ED based on "new baseline AMPs in the first full quarter following launch, likely the second quarter of 2015," and that Ipsen would "proceed with this approach absent CMS instruction to the contrary." *Id.* 4.

CMS responded on July 2, 2015, by an email from Wendy Tuttle, a Health Insurance Specialist with CMS's Pharmacy Division. A.R. 6–7. Tuttle acknowledged the various enhancements that Ipsen had made to Somatuline, but concluded that "these factors do not meet the criteria for the establishment of new base date AMPs for the three strengths of Somatuline ED." *Id.* 6. She explained that "[s]ections 1927(c)(2)(A) and (B) of the [Medicaid Act] specify that the baseline data is established for *each dosage form and strength* of the drug." *Id.* (emphasis in original). Accordingly, Tuttle rejected the argument that the Somatuline ED products approved under the two sNDAs discussed above should have their own base date AMPs, "because the final dosage form and strengths of each have remained the same." *Id.* "Upon our review of the information listed with FDA for the three strengths of Somatuline Depot, which are all approved under the same NDA number 022074," she concluded, "we believe that the baseline information for each strength of Somatuline ED should be the same as the baseline data for the correlating strength of the original Somatuline Depot." *Id.*

On September 21, 2015, Ipsen's lawyers wrote to the General Counsel of HHS, requesting a meeting to discuss Ipsen's "entitlement" to unique base date AMPs for its Somatuline ED products. A.R. 9. The letter first noted that Ipsen had "conducted extensive and

costly research to support significant improvements to its Somatuline products." *Id.* 10. It then argued that CMS's determination that Ipsen was not entitled to unique base date AMPs for Somatuline ED violated the Medicaid Act because Somatuline ED constituted a distinct "covered outpatient drug" under that statute. *Id.* 11–20. Specifically, Ipsen argued that the definition of "covered outpatient drug" in section 1927 of the Medicaid Act specifically referenced the FDCA's framework for the approval of new drugs, *id.* 12–14, and that Somatuline ED constituted a "new drug" under that framework, *id.* 14–20. Accordingly, the letter concluded, "CMS . . . should reconsider its decision reflected in the July 2, 2015 email and should approve Ipsen's request to establish new base date AMPs for its Somatuline ED product." *Id.* 21.

CMS responded by a letter dated August 3, 2016 from Dr. John Coster, Director of CMS's Pharmacy Division.[3] A.R. 33–34. Coster acknowledged that "section 1927(k)(2) of the Act defines a 'covered outpatient drug' based on FDA approval," but stated that CMS had found "no indication that Congress intended that FDA approval status be used for determining whether a drug qualifies as a new drug for the purposes of price reporting for the [Medicaid rebate program]." *Id.* 33–34. Coster noted that the Medicaid Act provides that baseline data should be established for each dosage form and strength of the drug, and concluded that "[t]he reasons for requiring a new approval for a drug that has new marketing authority do not require different Medicaid pricing policies when the dosage form and strength are not changed." *Id.* 34. Because the "new" Somatuline ED products had the same dosage form and strengths as the original Somatuline products, and because all of these versions of Somatuline had been approved under

[3] Dr. Coster's letter copied the General Counsel of HHS and Ipsen's General Counsel for North America. A.R. 34.

the same NDA number, Coster reaffirmed CMS's denial of Ipsen's request for new base date AMPs. *Id.*

With regard to the relevance of the sNDAs that FDA had approved for Somatuline ED, Coster concluded, "[c]onsistent with the statutory language, we consider a sNDA which contains the same 'route number' with an extension (indicating that it is a supplement to the NDA) to be approved under the same NDA, and such products should not have separate baseline data." Coster cited CMS's previous conclusion to that effect in Manufacturer Release No. 26, which stated that "baseline information, such as Market Date and Baseline AMP[,] MUST follow the NDA of the product." *Id.* (emphasis in original). Finally, Coster acknowledged the enhancements that Ipsen had made to Somatuline, but concluded that "these are not factors included in the statutory criteria for determining whether a drug qualifies as a new drug for the purposes of price reporting for the [Medicaid rebate program]," and thus the changes did "not warrant establishment of new base date AMPs for the three strengths of Somatuline ED." *Id.*

C. Procedural History

Ipsen filed its complaint on December 5, 2016. Compl. Ipsen claims that CMS's determination that Ipsen was not entitled to establish unique base date AMPs for Somatuline ED violated the APA's prohibition on agency action that is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A). Ipsen argues that CMS's determination was "contrary to law and in excess of CMS's authority" because the relevant provision of the Medicaid Act defines "covered outpatient drug" with reference to the FDCA, and Somatuline ED constituted a "new drug" under the relevant FDCA provisions. Compl. ¶ 75. Ipsen also argues that CMS's determination was "arbitrary and capricious" because CMS had drawn an arbitrary distinction between drug approvals obtained via NDAs and

those obtained via sNDAs, and because CMS had failed to meet the requirements of reasoned decisionmaking. *Id.* ¶ 76, 77.

The parties filed cross-motions for summary judgment. *See* Dkt. 13 (Ipsen); Dkt. 16 (Secretary). On September 24, 2018, the Court denied Ipsen's motion for summary judgment and granted the Secretary's cross-motion for summary judgment. Dkt. 23 (Order). The Court concluded that CMS's letter to Ipsen did not constitute "final agency action" subject to judicial review under the APA. Dkt. 24 (Mem. Op.) at 13; *see* 5 U.S.C. § 704 (providing for judicial review of "final agency action for which there is no other adequate remedy in a court").

On December 3, 2019, the D.C. Circuit reversed. *Ipsen Biopharm., Inc. v. Azar*, 943 F.3d 953, 959 (D.C. Cir. 2019). The D.C. Circuit concluded that CMS's letter had resulted in an "increased risk of prosecution and penalties" for Ipsen and therefore did constitute final agency action under the Supreme Court's decision in *Bennett v. Spear*, 520 U.S. 154 (1997). *Ipsen*, 943 F.3d at 957; *see Bennett*, 520 U.S. at 178 ("final agency action" is "one by which rights or obligations have been determined, or from which legal consequences will flow" (internal quotation marks and citation omitted)). The D.C. Circuit thus reversed the grant of summary judgment to the Secretary and remanded for further proceedings. *Ipsen*, 943 F.3d at 959.

On remand, the Court afforded the parties the opportunity for supplemental briefing. *See* Minute Order of Feb. 10, 2020. Having received and considered supplemental briefs from both parties, the Court will now consider the merits of the parties' renewed cross-motions for summary judgment. *See* Dkt. 33 (Ipsen); Dkt. 34 (Secretary).

II. LEGAL STANDARDS

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material fact and the

movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 247–48 (1986). A "material" fact is one that could affect the outcome of the lawsuit. *See Liberty Lobby*, 477 U.S. at 248; *Holcomb v. Powell*, 433 F.3d 889, 895 (D.C. Cir. 2006). A dispute is "genuine" if a reasonable jury could determine that the evidence warrants a verdict for the nonmoving party. *See Liberty Lobby*, 477 U.S. at 248; *Holcomb*, 433 F.3d at 895. In reviewing the record, the court "must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods.*, 530 U.S. 133, 150 (2000).

Under the APA, a reviewing court shall "hold unlawful and set aside" any aspect of a final agency action that is "arbitrary [and] capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In an APA challenge to final agency action, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). In other words, "the entire case . . . is a question of law" and the district court "sits as an appellate tribunal." *Am. Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (footnote and internal quotation marks omitted).

Arbitrary and capricious review is "fundamentally deferential—especially with respect to matters relating to an agency's areas of technical expertise." *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012) (alteration adopted and internal quotation marks omitted). A court "is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983). Rather, its review is limited to whether the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an

important aspect of the problem, offered 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." *Agape Church v. FCC*, 738 F.3d 397, 410 (D.C. Cir. 2013) (quoting *State Farm*, 463 U.S. at 43). Courts determine only whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *State Farm*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

In conducting this inquiry, a court does "not look at the agency's decision as would a scientist, but as a reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality." *Am. Trucking Ass'ns v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 249 (D.C. Cir. 2013) (alteration adopted and internal quotation marks omitted); *see also Chem. Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1263 (D.C. Cir. 1994) (describing the standard as "indulgent"). It is well established that a court "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). However, it is also well established 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). "Even an agency 'decision of less than ideal clarity' should be upheld 'if the agency's path may be reasonably discerned.'" *Anacostia Riverkeeper, Inc. v. Jackson*, 798 F. Supp. 2d 210, 222 (D.D.C. 2011) (quoting *State Farm*, 463 U.S. at 43).

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). The party challenging an agency's action as arbitrary and capricious bears the burden of proof. *Pierce v. SEC*, 786 F.3d 1027, 1035 (D.C. Cir. 2015).

III. ANALYSIS

Ipsen makes two arguments against CMS's decision not to update its base date AMPs for Somatuline. First, Ipsen argues that CMS's interpretation of the statutory and regulatory provisions that govern the Medicaid rebate program is contrary to law. Ipsen Mot. for Summ. J. at 15–20. Second, Ipsen argues that CMS's decision not to update its base date AMPs for Somatuline was arbitrary and capricious. *Id.* at 20–28. The Court will consider each of these arguments in turn.

A. Contrary to Law

1. Chevron *Deference*

As a threshold matter, the parties dispute whether CMS's interpretation is entitled to *Chevron* deference. *See, e.g.*, Ipsen Mot. for Summ. J. at 13; CMS Cross-Mot. for Summ. J. at 15. An agency's interpretation is entitled to *Chevron* deference where "Congress [has] delegated authority to the agency generally to make rules carrying the force of law" and "the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). "Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference." *Christensen v. Harris County*, 529 U.S. 576, 587 (2000).

For three principal reasons, the interpretation of the Medicaid Act articulated in CMS's letter to Ipsen is not entitled to *Chevron* deference. First, CMS declined to promulgate its interpretation pursuant to any formal administrative procedures. While agency interpretations announced in informal adjudication may sometimes receive *Chevron* deference, CMS's failure to employ "those 'relatively formal administrative procedure[s]' that 'tend[] to foster the fairness and deliberation that should underlie a pronouncement' of legal interpretation weighs against the application of *Chevron* deference." *Fogo De Chao (Holdings) Inc. v. U.S. Dep't of Homeland Sec.*, 769 F.3d 1127, 1136-37 (D.C. Cir. 2014) (quoting *Mead*, 533 U.S. at 230); *see also FEC v. Nat'l Rifle Ass'n*, 254 F.3d 173, 185 (D.C. Cir. 2001) ("[v]irtually every relevant post-*Christensen* decision has declined to give *Chevron* deference to just this type of informal agency action," namely, a letter issued "pursuant to informal agency procedures"). Second, CMS's letter to Ipsen demonstrates on its face that it was not "intended to have general applicability and the force of law," as it was "singularly focused on" one regulated entity and "did not purport to set policy for future . . . determinations." *Kaufman v. Nielsen*, 896 F.3d 475, 484 (D.C. Cir. 2018) (internal quotation marks omitted). Indeed, CMS did not even release the letter publicly and, accordingly, other regulated parties do not even have access to it. Third, CMS's letter was not issued by the head of CMS, but instead by a mid-level agency official. *See id.* at 484–85. Taken together, these factors strongly suggest that the interpretation of the Medicaid Act articulated in CMS's non-public letter to Ipsen was not "promulgated in the exercise of [CMS's rulemaking] authority," *Mead*, 53 U.S. at 227, and that *Chevron* deference therefore does not apply.

In urging the opposite conclusion, CMS relies heavily on the factors set forth in *Barnhart v. Walton*, 535 U.S. 212 (2002), namely, "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the

complexity of that administration, and the careful consideration the Agency has given the question over a long period of time." *Id.* at 222. To begin with, these are not the exclusive factors for determining whether *Chevron* deference applies to an agency's interpretation. *See id.* ("*In this case* . . . [these five factors] all indicate that *Chevron* provides the appropriate legal lens through which to view the legality of the Agency interpretation here at issue." (emphasis added)). Even those D.C. Circuit cases that have explicitly applied the *Barnhart* factors have also weighed other considerations that place greater emphasis on the procedural means and context of the agency's interpretation than on the nature of the statutory question itself. *See, e.g.*, *Kaufman*, 896 F.3d at 484 (applying the *Barnhart* factors but also considering whether the agency interpretation was "clearly intended to have general applicability and the force of law" (quoting *Fox*, 684 F.3d at 78)). In any event, not all of the *Barnhart* factors support the application of *Chevron* deference here because CMS's two-page letter to Ipsen does not evidence "careful consideration . . . over a long period of time." *Barnhart*, 535 U.S. at 222. To the contrary, the letter suggests a one-off explanation of CMS's understanding of the statute, articulated in an informal context that does not indicate that CMS "intended [it] to have general applicability and the force of law." *Fox*, 684 F.3d at 78.

For the foregoing reasons, CMS's interpretation does not merit *Chevron* deference. Absent such deference, the Court will "proceed to determine the meaning of [the Medicaid Act] the old-fashioned way," *Miller v. Clinton*, 687 F.3d 1332, 1342 (D.C. Cir. 2012), by tackling the interpretive question head-on and determining the best reading of the statute for itself.

2. *The Merits*

On the merits of the statutory question at issue, CMS interprets the relevant provisions to allow manufacturers to establish new base date AMPs for a given drug under two circumstances.

First, the Medicaid Act itself states that the amount of the rebate is calculated "with respect to each *dosage form* and *strength* of a single source drug or an innovator multiple source drug." 42 U.S.C. § 1396r-8(c)(2)(A) (emphasis added). According to the explicit command of the statute, if the manufacturer obtains approval for a new dosage form or strength of a drug, it is automatically entitled to establish a new base date AMP corresponding to that particular dosage form or strength of the drug. Absent those circumstances, CMS argues, the manufacturer may establish new base date AMPs only upon obtaining FDA approval of a new NDA pursuant to section 505 of the FDCA. That is because, under CMS's interpretation, only such approval gives rise to a new "covered outpatient drug" under the terms of the Medicaid Act. *See id.* § 1396r-8(k)(2). CMS's letters to Ipsen articulate this interpretation of the relevant provisions. *See* A.R. 34 (manufacturer is not entitled to establish new base AMPs where the new drug products "have the same dosage form and strengths of the original . . . products" and were "approved under the same NDA").

Several pieces of evidence from the statutory and regulatory framework demonstrate that CMS's interpretation of the relevant provisions is the best one. First and most importantly, the interpretation follows straightforwardly from the text of the Medicaid Act. The Act's rebate requirement applies to all "covered outpatient drugs," *see* 42 U.S.C. § 1396r-8(a), and the Act defines "covered outpatient drug" as "a drug . . . which is approved for safety and effectiveness as a prescription drug under section 505" of the FDCA, *id.* § 1396r-8(k)(2). Pursuant to section 505(b) of the FDCA, Ipsen submitted a NDA for Somatuline in October 2006, *see* A.R. 35, and the FDA approved that NDA on August 30, 2007, *see id.* 40. Once Ipsen obtained FDA approval of the Somatuline NDA, Somatuline became "a drug . . . which is approved for safety and effectiveness as a prescription drug under section 505" of the FDCA. 42 U.S.C. § 1396r-

8(k)(2). Therefore, subsequent changes to Somatuline approved via supplemental filings did not establish a new "covered outpatient drug" for purposes of the Medicaid Act because the underlying product—Somatuline—already satisfied the condition that it be "approved for safety and effectiveness . . . under section 505" of the FDCA. *Id.*

Furthermore, the additional rebate calculation provision at issue applies to two particular types of covered outpatient drugs—"single source drug[s]" and "innovator multiple-source drug[s]," *see id.* § 1396r-8(c)(2)(A) —and the Medicaid Act's definitions of those terms further support CMS's interpretation. The Act defines "single source drug" as "a covered outpatient drug . . . which is produced or distributed under a new drug application approved by [FDA]," *id.* § 1396r-8(k)(7)(iv), and an "innovator multiple source drug" as "a multiple source drug that is marketed under a new drug application approved by [FDA]," *id.* § 1396r-8(k)(7)(ii). The specific references in both definitions to a "new drug application" support CMS's conclusion that Somatuline, the subject of the original NDA that FDA approved in 2007—and not its multiple, subsequent, merely *improved* iterations—is the relevant unit for purposes of Ipsen's rebate calculation. The Medicaid Act's implementing regulations further buttress that conclusion. The regulatory definitions for both of the above-referenced categories of drugs specifically reference "an *original* new drug application (NDA) approved by FDA," 42 C.F.R. § 447.502 (emphasis added), and the definition of a "single-source drug" is even linked to "an approved NDA number issued by FDA," *id.* These definitions further undermine the notion that subsequent changes to an original NDA—such as those approved through the sNDA process—could establish a new drug for purposes of calculating Ipsen's additional-rebate liability.

Finally, the contrast between NDAs and sNDAs makes clear that only the former (absent a change to the dosage form or strength of the drug) can give rise to a new "covered outpatient

drug" for purposes of Medicaid rebate calculations. Just as the name suggests, sNDAs are *supplements* to preexisting drug applications that FDA *has already approved*. That is clearly reflected in the FDCA's implementing regulations defining and authorizing sNDAs, which establish a separate approval process that applies whenever a manufacturer wishes to make "[s]upplements and other changes *to an approved NDA*." 21 C.F.R. § 314.70 (emphasis added). The entire sNDA process therefore presumes that there is an existing NDA to supplement. And the changes that require a manufacturer to submit a sNDA are those that might adversely affect various characteristics "*of the drug product* as these factors may relate to the safety or effectiveness *of the drug product*." *Id.* § 314.70(b) (emphasis added). The sNDA requirement, therefore, also assumes that there is an existing drug that might be adversely affected by the proposed changes. In light of these provisions, while Ipsen might be correct to argue that sNDAs are "approved for safety and effectiveness . . . under section 505" of the FDCA, 42 U.S.C. § 1396r-8(k)(2), a sNDA does not establish a unique "*drug* . . . approved for safety and effectiveness . . . under section 505," *id.* (emphasis added), because it merely adds to a preexisting drug. For the above reasons, CMS's interpretation of the statutory framework is the best one: absent a change to the drug's dosage form or strength, a new drug for Medicaid rebate purposes is defined by the FDA's approval of a new drug application under section 505 of the FDCA.[4]

[4] While the Court adopts CMS's interpretation without affording it the benefit of deference, the Court notes for the record the consistency of this interpretation with CMS's practice of treating NDA approval as determinative of base date information for Medicaid rebate calculation purposes. *See, e.g.*, A.R. 91 ("Baseline information, such as Market Date and Baseline AMP MUST follow the NDA of the product." (emphasis in original)). Moreover, while no other court has squarely addressed this issue before now, this Court has previously speculated that the unchallenged nature of CMS's approach in this general arena "might be because the statute is clear." *Mallinkcrodt ARD LLC v. Verma, et al.*, 19-cv-1471 (TFH), Dkt. 46 (Mem. Op.) at 22.

Ipsen poses many objections to CMS's interpretation, but all are ultimately unavailing. *First*, Ipsen argues that "the [Medicaid] Act makes clear that Congress intended that CMS look to the existing FDCA regime" when administering the Medicaid rebate program. Ipsen Mot. for Summ. J. at 15. It is true that the Act frequently directs CMS to the FDCA or FDA regulations in administering Medicaid, but the Act does so only in specific circumstances delineated in the statutory text. *See, e.g.*, 42 U.S.C. § 1396r-8(a)(3)(A)(ii) (requiring payment for a drug only if FDA has given the drug a particular rating); *id.* § 1396r-8(e)(4) (setting a reimbursement limit for certain drugs that FDA has rated "therapeutically and pharmaceutically equivalent" to other drugs). The Medicaid Act does not adopt the entire FDCA wholesale, and this case deals with a particular provision of the Medicaid Act that refers to "a drug which is approved for safety and effectiveness as a prescription drug under section 505" of the FDCA. 42 U.S.C. § 1396r-8(k)(2). For the reasons described above, CMS correctly interpreted that provision to refer to a drug approved under section 505 pursuant to an original NDA, and not to subsequent, altered versions of a preexisting drug where changes from the original version were approved by supplements to the original NDA.

Second, Ipsen points to the FDCA's "Definitions" section, which defines the term "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). This provision favors Ipsen because the language of the definition seemingly links the standard for a "new drug" to the proven safety and effectiveness of the conditions of use listed on the product's label, and some of the changes for which Ipsen obtained approval by sNDA—most notably,

Somatuline's new indication for the treatment of GEP-NETs—did require changes to those conditions of use. Nevertheless, this definition does not overcome CMS's interpretation of the overall statutory and regulatory scheme for several reasons.

First and most importantly, the Medicaid Act—the ultimate authority on the question of Ipsen's entitlement to new base date AMPs for Somatuline—does not incorporate this definition from the FDCA. Instead, the Medicaid Act defines "covered outpatient drug" as "a drug . . . which is approved for safety and effectiveness as a prescription drug *under section 505*" of the FDCA. 42 U.S.C. § 1396r-8(k)(2) (emphasis added). For the reasons described above, that means that a distinct "drug" for Medicaid rebate purposes is defined by FDA's approval of a distinct NDA pursuant to section 505.

Moreover, Ipsen's reliance on the definition of "new drug" in the FDCA proves too much. An enormous number of potential changes to a drug product would require a manufacturer to obtain FDA approval for changes to the conditions of use listed on a drug product's label. Some such changes—for example, changes to the recommendations for patient monitoring, 21 C.F.R. § 201.57(a)(10), or the recommended use by specific populations, *id.* § 201.57(a)(13)—would surely not automatically entitle a manufacturer to declare a "new drug" for Medicaid rebate purposes. But taking the FDCA's definition of "new drug" as the ultimate basis for a manufacturer's entitlement to new base date AMPs would require precisely that result.

Furthermore, relying on the FDCA's definition of a "new drug" in determining a manufacturer's eligibility for new base date AMPs would render at least one aspect of the Medicaid Act mere surplusage. Recall that the Act specifically directs manufacturers to establish new base date AMPs for each distinct "dosage form" and "strength" of a drug. *See* 42 U.S.C.

§ 1396r-8(c)(2). But changes to "dosage form" and "strength" would plainly establish a "new drug" under the FDCA's definition, and therefore, under Ipsen's argument, would already establish new base date AMPs absent that provision of the Medicaid Act. If Ipsen were correct that the Medicaid Act incorporates the FDCA's definition of "new drug" wholesale, then the Medicaid Act's specific references to "dosage form" and "strength" would be unnecessary. "It is . . . a cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute." *Williams v. Taylor*, 529 U.S. 362, 404 (2000) (internal quotation marks omitted). The references to "dosage form" and "strength" in the Medicaid Act's rebate-calculation provisions therefore suggest that Congress did not intend CMS to rely on the FDCA's definition of "new drug" when calculating manufacturers' rebate obligations under those provisions. In short, taking into account the fact that the Medicaid Act does not incorporate the FDCA's definition of "new drug," as well as the inconsistency of that definition with other features of the statutory and regulatory scheme at issue here, CMS interpreted the relevant provisions correctly notwithstanding that definition.

Third, Ipsen objects that CMS's position—that approval of a NDA, but not a sNDA, entitles the manufacturer to set new base date AMPs—is "arbitrary" and "untethered" to any statutory provision. *See, e.g.*, Mot. for Summ. J. at 20 ("It is an utterly arbitrary distinction given that a manufacturer is legally permitted to proceed via either avenue."). For the reasons stated above, CMS's position is not untethered to statute, but is instead required by section 1396r-8 of the Medicaid Act and section 505 of the FDCA. To the extent Ipsen finds the significance of a FDA-approved NDA "arbitrary," its quarrel is with Congress, not CMS. Moreover, Ipsen is wrong to the extent that it suggests that CMS's interpretation would prevent manufacturers from resetting their base date information for substantial changes approved via sNDA while permitting

them to do so for trivial changes approved via NDA. *See, e.g.*, Dkt 31 (Ipsen Suppl. Reply.) at 4. Under CMS's interpretation, a new NDA (absent changes to the drug's dosage form or strength) is necessary, *but not always sufficient*, to establish new base date information for Medicaid rebate purposes. Minor changes approved via NDA—to the extent that FDA regulations even permit such approvals—might well fail to establish a new "covered outpatient drug" under certain circumstances. *Cf.* Dkt. 32 (CMS Sur-Reply) at 3 n.1 ("[T]here is no evidence in the record of how the FDA would treat an application to make changes to an existing drug product where the manufacturer submits a new NDA but could permissibly have submitted a supplemental NDA.").

Fourth, Ipsen argues that it should be entitled to reset its base date AMPs for Somatuline because the research it conducted to establish Somatuline's new indication for GEP-NETs entitled it to three years of "new drug product exclusivity" under the FDCA. *See, e.g.*, Mot. for Summ. J. at 16. As a result, for the next three years, FDA will not approve another drug manufacturer's application based on the same clinical trials that Ipsen conducted to support Somatuline's new indication. *See* 21 U.S.C. 355(c)(3)(E)(iii). This argument does not undermine CMS's interpretation. To begin with, the phrase "new drug product exclusivity" is a term used by Ipsen, not by the actual statutory provision that entitles Ipsen to that benefit. *See id.* Moreover, the fact that Congress conferred this particular benefit upon drug manufacturers in order to incentivize the substantial investments necessary to approve a drug for a new indication does not mean that Congress also intended to incentivize such investments by reducing manufacturers' Medicaid rebate obligations to the states. To the contrary, if anything, the inclusion of an *express* provision granting "new drug product exclusivity" to manufacturers in

Ipsen's position suggests that Congress did not *impliedly* provide additional incentives elsewhere in the statutory scheme.

Fifth, Ipsen points to recent amendments to the Medicaid Act that alter the rebate calculation for "a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form." 42 U.S.C. § 1396r-8(c)(2)(C). Under these amendments, in effect, the manufacturer's rebate liability for the new "line extension" reverts to the highest additional rebate of the original drug product. *See id.* Congress added these provisions to the Act in order to prevent drug manufacturers from "avoid[ing] incurring additional rebate obligations by making slight alterations to existing products, sometimes called line extensions." S. Rep. No. 111-89 (2009). According to Ipsen, these amendments reveal Congress's background understanding that under the Medicaid Act, "modifications to existing drugs . . . are generally considered new products for purposes of reporting AMPs to CMS." *Id.* Because Congress chose to alter this background principle explicitly for "line extension[s]" of drugs in "oral solid dosage form," 42 U.S.C. § 1396r-8(c)(2)(C), Ipsen contends, that principle remains in place for injectable drugs like Somatuline. *See* Mot. for Summ. J. at 19–20.

But the "line-extension amendments" are not inconsistent with CMS's interpretation. For one thing, the amendments prevent manufacturers from making minor changes to existing drugs through the NDA (rather than sNDA) process, and then claiming entitlement to new base date AMPs on that basis. As discussed above, that remains at least a potential loophole under CMS's interpretation of the statutory scheme, one that the line-extension amendments have definitively closed for "oral solid dosage form" drugs. For another, the amendments appear to be aimed at "extended release formulations" of preexisting drugs, *see* 42 U.S.C. § 1396r-8(c)(2)(C) (defining "line extension" as "a new formulation of the drug, such as an extended release formulation"),

which typically involve changes to the dosage form or strength of a drug. Given the clear terms of the Medicaid Act requiring new base date information for a new dosage form or strength of a drug, *see id.* § 1396r-8(c)(2)(A), those changes would also entitle a manufacturer to new base date AMPs under CMS's interpretation. In these circumstances, too, the line-extension amendments prevent that outcome for new versions of "oral solid dosage form" drugs. Thus, the amendments do not reveal a baseline statutory principle that contradicts CMS's theory.

More generally, the Supreme Court has "frequently cautioned that it is at best treacherous to find in congressional silence alone the adoption of a controlling rule of law." *United States v. Wells*, 519 U.S. 482, 496 (1997) (quoting *NLRB v. Plasterers' Local Union No. 79*, 404 U.S. 116, 129–30 (1971) (internal quotation marks omitted); *see also Burns v. United States*, 501 U.S. 129, 136 (1991) ("[A]n inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent."). Given the broader statutory context described in detail above, Ipsen relies too heavily on a contestable inference from a statutory provision that ultimately does not even address the type of drug (injectable) at issue in this dispute.

Finally, Ipsen points to two of CMS's own regulatory releases. As Ipsen interprets these items, both demonstrate that a new national drug code (NDC) can establish a new "drug" for Medicaid rebate purposes or otherwise entitle a manufacturer to establish new base date information even absent FDA's approval of a new NDA.[5] First, Ipsen points to a CMS regulation that defines "bundled sale" as "any arrangement regardless of physical packaging

[5] It is worth noting, at the outset, that this theory is expressly contradicted by the great weight of CMS's regulatory output, which repeatedly establishes that "[b]aseline information, such as Market Date and Baseline AMP MUST follow the NDA of the product" and "does NOT follow the NDC of the product." A.R. 91–92 (CMS Release No. 26); *see also id.* 100 (Release No. 38) (same); *id.* 110 (Release No. 48) (same).

under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug [or] drugs of different types (that is, at the nine-digit national drug code (NDC) level)." 42 C.F.R. § 447.502. Ipsen argues that if "drugs of different types" are defined by new NDCs, rather than FDA-approved NDAs, Ipsen should be allowed to reset its base date information without obtaining the latter form of approval. But Ipsen relies much too heavily on the phrase "drugs of different types," which is not defined in the regulation and does not preclude the possibility that several "drugs of different types," in the context of a "bundled sale," may nonetheless constitute a single "covered outpatient drug" for Medicaid rebate purposes. *See* 42 U.S.C. § 1396r-8(k)(2).

Ipsen also relies on CMS Release No. 48, which states that when a company "buys a product, changes something . . . and applies for an ANDA, the NDC that reflects the product under the new ANDA has history start over for itself." A.R. 110. An aNDA—a required form of approval for generic drugs that is not at issue in this litigation—is approved under section 505(j) of the FDCA, and the Medicaid Act explicitly provides that approval under that section gives rise to a new "covered outpatient drug." 42 U.S.C. § 1396r-8(k)(2). Therefore, Release No. 48 is consistent with the express terms of the Medicaid Act and does not contradict CMS's interpretation. In short, these two regulatory items provide little, if any, support for Ipsen's challenge to CMS's interpretation.

In sum, CMS has offered the best interpretation of a complex statutory and regulatory scheme: absent a change to the dosage form or strength of a drug, *id.* § 1396r-8(c)(2)(A), or FDA's approval of a new NDA (or aNDA) under section 505 of the FDCA, *see id.* § 1396r-8(k)(2), a given drug product remains the same "covered outpatient drug" under the Medicaid Act and the drug manufacturer is not entitled to reset base date AMPs for the product.

Accordingly, the Court will reject Ipsen's argument that CMS's interpretation of the relevant provisions is contrary to law.

B. Arbitrary and Capricious

Ipsen also argues that CMS's ultimate decision—that Ipsen would not be allowed to reset its base date AMPs for Somatuline—was arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A). Arbitrary-and-capricious review asks whether the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered 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." *Agape Church*, 738 F.3d at 410 (quoting *State Farm*, 463 U.S. at 43). The agency's decision need not "be a model of analytic precision to survive a challenge," *Dickson*, 68 F.3d at 1404, and "[e]ven an agency 'decision of less than ideal clarity' should be upheld 'if the agency's path may be reasonably discerned,'" *Anacostia Riverkeeper, Inc.*, 798 F. Supp. 2d at 222 (quoting *State Farm*, 463 U.S. at 43).

Ipsen argues, first and most strenuously, that CMS acted arbitrarily and capriciously because it failed to adequately justify its decision. Ipsen Mot. for Summ. J. at 21–24. In particular, Ipsen argues, CMS relied exclusively on the fact that Somatuline ED shared the same dosage form and strengths as the original Somatuline, while failing to consider the more nuanced statutory question of whether Somatuline nonetheless constituted a new "covered outpatient drug." But in Coster's August 3, 2016 letter, CMS acknowledged and responded to Ipsen's statutory argument. In that letter, CMS reasoned that "[c]onsistent with the statutory language, we consider a sNDA which contains the same 'route number' with an extension (indicating that it is a supplement to the NDA) to be approved under the same NDA, and such products should

not have separate baseline data." A.R. 34. The agency further explained that "[t]he reasons for requiring a new approval for a drug that has new marketing authority [*i.e.*, a sNDA] do not require different Medicaid pricing policies when the dosage form and strength are not changed." *Id.* 34. These statements surpass the lenient arbitrary-and-capricious threshold for agency decisionmaking. While the agency certainly could have engaged in a more robust statutory analysis, "[e]ven an agency 'decision of less than ideal clarity' should be upheld 'if the agency's path may be reasonably discerned,'" *Anacostia Riverkeeper*, 798 F. Supp. 2d at 222. CMS's path can be reasonably discerned here, as the agency considered the statutory text and concluded that the approval of a sNDA for a preexisting drug would not suffice to establish a new drug for Medicaid rebate purposes absent a change to the drug's dosage form or strength.[6]

Ipsen also argues that CMS failed to provide Ipsen with fair notice of its interpretation. Ipsen Mot. for Summ. J. at 25–27. At the outset, this argument is difficult to accept given that Ipsen's *initial* letter to CMS requesting permission to establish new base date AMPs articulated the agency's interpretation accurately and precisely. *See* A.R. 2 n.5 ("CMS has often stated that the baseline AMP '*follows the NDA*, not the NDC.' The releases are very specific about following the *NDA*, and a supplemental NDA is distinct from an NDA." (citation omitted)

[6] CMS's reliance on the statutory text, as demonstrated by the above quotations, also answers Ipsen's criticism that CMS unduly relied on the purportedly inapposite CMS Release No. 26, which states that "[b]aseline information, such as Market Date and Baseline AMP MUST follow the NDA of the product" and "does NOT follow the NDC of the product." A.R. 91–92 (emphasis in original). CMS's decision to deny Ipsen's request ultimately derived from CMS's interpretation of the overall statutory framework governing Medicaid rebate calculations. While CMS cited Release No. 26 in support of that decision, its decision did not hinge on that release. In any event, Release No. 26 is not inapposite to the statutory question at issue, as Ipsen contends. *See* Ipsen Mot. for Summ. J. at 21–23. While Release No. 26 addresses a technically distinct factual situation—where one company purchases a FDA-approved drug from another company—it articulates a general principle that base date information "follows the NDA of the product," A.R. 91, and CMS reasonably viewed that principle as extending more broadly to encompass the circumstances presented by Ipsen's changes to Somatuline.

(emphasis in original)). The administrative record therefore belies any suggestion that Ipsen was caught unaware when it discovered CMS's view.

In any event, CMS provided notice of its interpretation in multiple public releases prior to its decision on Ipsen's particular case. *See* A.R. 91 (Release No. 26) ("Baseline information, such as Market Date and Baseline AMP MUST follow the NDA of the product"); *id.* 100 (Release No. 38) ("Baseline information . . . MUST follow the NDA of the product"); *id.* 105 (Release No. 43) (similar) ("[P]rovide information such as . . . Market Date (of the NDA) . . ."); *id.* 110 (Release No. 48) ("History follows the NDA, NOT the NDC of the product"). While these releases addressed different factual circumstances than those at issue in this dispute, they nevertheless consistently articulated the general principle that base date information would "follow the NDA" of the drug—and Ipsen recognized the potential applicability of that principle in its initial letter to CMS, *see id.* 2 n.5. This degree of notice adequately discharged CMS's obligations under the lenient standards of the APA.

Next, Ipsen points to other instances in which manufacturers sought to obtain CMS's approval to update the base date AMPs for their drugs. In some of those cases, CMS consulted with FDA about whether the modifications at issue sufficed to establish a new drug. *See, e.g.*, A.R. 123–25. Ipsen argues that CMS's failure to consult FDA in the same manner regarding the changes to Somatuline rendered CMS's decision arbitrary and capricious. But Ipsen's argument concerns CMS's internal deliberative processes, and CMS is not obligated to employ the same deliberative processes in each case, so long as each decision is supported by the information before it. *See Fox*, 684 F.3d 67, 74–75. In pressing its argument to the contrary, Ipsen relies heavily on *Wilhelmus v. Geren*, 796 F. Supp. 2d 157 (D.D.C. 2011). But *Wilhelmus* concerned an agency's failure to distinguish its own on-point precedent, which required remand because it

violated the agency's obligation to reach similar results for similarly situated parties. *Id.* at 162–63. *Wilhelmus* says nothing about an agency's obligation to employ the same deliberative processes in every case. And Ipsen has not alleged that it is similarly situated to any manufacturers for whom CMS reached a different result.

Finally, Ipsen repackages two of its arguments against CMS's legal interpretation as arbitrary-and-capricious claims. First, Ipsen, argues that CMS acted arbitrarily and capriciously because it failed to consider its own contrary guidance purportedly contained in CMS Release No. 48 and in 42 C.F.R. § 447.502, the regulation defining the term "bundled sale." Ipsen Mot. for Summ. J. at 22–23. For the reasons described above, these provisions have little to no significance to the interpretive question before the agency. But in any event, Ipsen waived any argument based on these two provisions by failing to raise them prior to its opening brief. *See Coburn v. McHugh*, 679 F.3d 924, 929 (D.C. Cir. 2009) (quoting *United States v. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952)) (referencing the "hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review").

Second, Ipsen argues that CMS's decision relied on a "substantively arbitrary" distinction between NDAs and sNDAs, Ipsen Mot. for Summ. J. at 25, and that therefore CMS has failed to articulate a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43. This argument fails for the reasons stated above in response to Ipsen's legal "arbitrariness" argument. In short, CMS's decision has a sound basis in the applicable statutory scheme: sNDAs reflect changes to preexisting "covered outpatient drugs" that have already been "approved for safety and effectiveness as a prescription drug under section 505" of the FDCA.

42 U.S.C. § 1396r-8(k)(2)(A)(i). Any arbitrariness that Ipsen sees in the resulting significance of NDAs (as opposed to sNDAs) is therefore attributable to Congress, not CMS.

CONCLUSION

For the foregoing reasons, the Court will grant CMS's Renewed Motion for Summary Judgment and deny Ipsen's Renewed Cross-Motion for Summary Judgment. A separate order consistent with this decision accompanies this memorandum opinion.

DABNEY L. FRIEDRICH
United States District Judge

June 19, 2020