UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STI PHARMA, LLC, *Plaintiff*, v. ALEX M. AZAR, II, *et al.*, *Defendants.*	Civil Action No. 18-1231 (RDM)

MEMORANDUM OPINION

When Congress added outpatient prescription drug coverage to the Medicaid program in 1990, it conditioned payment for prescription drugs on each manufacturer's agreement to participate in the Medicaid Drug Rebate Program ("MDRP"). Under the terms of the MDRP, the percentage of the cost of the drug used to calculate the rebate that drug manufacturers must pay to participating states is determined, in part, based on which of three categories the drug falls under: (1) single source, (2) innovator multiple source, or (3) noninnovator multiple source drugs. 42 U.S.C. § 1396r-8(k)(7)(A)(ii)–(iv) (2012 version).[1] This categorization is a matter of importance to drug manufacturers because the rebate percentage a manufacturer must pay is higher for a single source or innovator multiple source drug than for a noninnovator multiple source drug. *Id.* §§ 1396r-8(c)(1)(A)–(B), 1396r-8(c)(3)(B). There is, in other words, a financial benefit under the MDRP for those manufacturers who market a noninnovator multiple source drug—they pay a lower rebate rate to state Medicaid agencies.

[1] For reasons explained below, all citations to 42 U.S.C. § 1396r-8 throughout this opinion will be to the 2012 version of the United States Code unless otherwise noted. The Court will also include the parenthetical "(2012 version)" where extra emphasis is appropriate.

Plaintiff STI Pharma, LLC ("STI Pharma") is the manufacturer of Sulfatrim Pediatric Suspension ("Sulfatrim"). AR 64. Before STI Pharma purchased the rights to market Sulfatrim in 2011, the drug was categorized as a noninnovator multiple source drug. But, based on what STI Pharma characterizes as a mistake, STI Pharma altered course and began categorizing the drug as an innovator multiple source drug, subject to the higher rebate requirement, Dkt. 15-1 at 22, until 2016 when Defendant Centers for Medicare & Medicaid Services ("CMS") issued a final rule that now—at least going forward— permits STI Pharma to categorize Sulfatrim as a noninnovator multiple source drug, AR 61–62. The parties disagree, however, about whether that categorization constitutes a new rule that CMS adopted as an exercise of its administrative discretion and that applies only prospectively or whether it represents the best view of the statute as it existed at all times relevant to this case, meaning that it applies retroactively as well.

The parties' dispute came to a head after STI Pharma requested that CMS change the categorization of Sulfatrim to a noninnovator multiple source drug for the period from the fourth quarter of 2013 through the first quarter of 2016. AR 56. CMS denied that request and denied STI Pharma's subsequent request for reconsideration of that determination. AR 61. Unsatisfied with that decision, STI Pharma brought this suit against the Department of Health and Human Services and CMS alleging that CMS's refusal to correct the categorization retrospectively was arbitrary and capricious, not in accordance with law, and in excess of the agency's statutory authority in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq*. Dkt. 1. The parties subsequently filed cross-motions for summary judgment addressing each of STI Pharma's claims. Dkt. 15; Dkt. 17.

For the reasons explained below, the Court concludes that, at the relevant times, the MDRP statute's noninnovator multiple source drug category is best construed to include

duplicate drugs, like Sulfatrim, that were approved under the "paper new drug application" process that the Food & Drug Administration ("FDA") used to evaluate certain non-pioneer drugs before Congress enacted the Hatch-Waxman Amendments in 1984. The Court will, accordingly, **GRANT** Plaintiff's motion for summary judgment, Dkt. 15, and will **DENY** Defendants' cross-motion for summary judgment, Dkt. 17, and will **REMAND** to CMS for further proceedings consistent with this opinion.

I. BACKGROUND

A. FDA Drug Approval and the Medicaid Drug Rebate Program

1. *New Drug Approval Process*

The Federal Food, Drug, and Cosmetic Act ("FFDCA") requires drug manufacturers to secure approval from the FDA prior to marketing any new drug, including new generic versions of existing drugs. 21 U.S.C. § 355(a); *see also AstraZeneca Pharm. v. FDA*, 850 F. Supp. 2d 230, 233 (D.D.C. 2012). Congress established a streamlined process for bringing new generic drugs to market in the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 U.S.C.), often referred to as the Hatch-Waxman Amendments. *AstraZeneca Pharm.*, 850 F. Supp. 2d at 233. Today, the FDA approval process typically takes one of two paths: (1) the "new drug application" or "NDA" process under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), and (2) the "abbreviated new drug application" or "ANDA" process under § 505(j) of the FFDCA, *id.* § 355(j). Drug manufacturers, in turn, have two options under the NDA process: they can either submit evidence based on their own clinical trials demonstrating the drug's safety and effectiveness pursuant to § 505(b)(1), or they can rely on literature produced by others that demonstrates the drug's safety and effectiveness pursuant to § 505(b)(2). *See Takeda Pharms., U.S.A., Inc. v.*

Burwell, 78 F. Supp. 3d 65, 71–72 (D.D.C. 2015). Under the ANDA process, drug manufacturers seeking approval of generic versions of previously approved drugs need not submit clinical studies proving the drug's safety or effectiveness but may, instead, demonstrate that the generic drug is, among other things, the chemical equivalent and bioequivalent of the relevant previously approved branded drug. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005); 5 U.S.C. § 355(j).

Prior to the passage of the Hatch-Waxman Amendments, the FDA employed another drug approval process called the "paper NDA process." *See Publication of "Paper NDA" Memorandum*, 46 Fed. Reg. 27,396 (May 19, 1981). This process applied in two situations. First, it applied to

> duplicate drug products of post-1962 drugs, *i.e.*, drug products which contained an active ingredient identical to an already marketed drug product first approved for marketing after 1962 in the same or closely related dosage form[] and offered for the same indications as those of the already marketed drug product.

Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,890 (Jul. 10, 1989).[2] A drug manufacturer seeking paper NDA approval for a duplicate drug could submit evidence of the drug's pharmaceutical equivalence and bioequivalence to a previously approved drug along with published reports establishing the safety and effectiveness of that previously approved drug. *See Hoffman-La Roche, Inc. v. Harris*, 484 F. Supp. 58, 61–62 (D.D.C. 1979); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–77 (1990). Second, in some cases, the paper NDA process also allowed drug manufacturers to secure approval for a pioneer drug based on literature establishing the safety and effectiveness of the new drug, "supplemented" with additional studies

[2] Prior to 1962, the FDA reviewed new drug applications for safety but not effectiveness. *United States v. Rutherford*, 442 U.S. 544, 556 (1979) ("[T]he 1962 Amendments incorporated an efficacy standard into the new drug application procedures.").

conducted by the applicant. *See Takeda Pharms.*, 78 F. Supp. 3d at 71–72; *Response to Petition Seeking Withdrawal of the Policy Described in the Agency's "Paper" NDA Memorandum of July 31, 1978*, 45 Fed. Reg. 82,052, 82,055 (Dec. 12, 1980) ("FDA has in some cases based its approval of pioneer NDA's on published reports supplemented by studies done by the manufacturers.").

The FDA abandoned the paper NDA process for duplicate drugs after enactment of the Hatch-Waxman Amendments because the new statutory scheme subsumed that process. *See* 54 Fed. Reg. at 28,890 ("Because the 1984 Amendments established a statutory scheme for the approval of all applications that, before the Amendments, would have been approved under the paper NDA policy, the agency believes that the policy is no longer necessary."). Going forward, the FDA would divide applications with the characteristics of former paper NDAs into two buckets. Section 505(b)(2) of the new statutory scheme would cover the rare paper NDA for a novel drug. Section 505(j) of the new statutory scheme provided for ANDAs, which supplanted the paper NDA process for duplicate drugs. Although similar, the process for approval of a post-Hatch-Waxman ANDA differs from the pre-Hatch-Waxman process for approval of a duplicate paper NDA because a paper NDA application required "studies of safety and effectiveness," which are not required in the ANDA process. *See* 54 Fed. Reg. at 28,890. Relevant here, the FDA resolved to treat future applications with the same characteristics as former duplicate paper NDAs as ANDAs. *Id.* (electing to treat "[a]pplications for duplicates of listed drugs eligible for approval under ANDA's [as] submitted under [§] 505(j) of the [A]ct rather than under [§] 505(b) of the [A]ct, even if [the] applications [were] supported by literature reports of safety and effectiveness"). But it did not set aside paper NDA approvals granted prior to enactment of the Hatch-Waxman Amendments or convert them into ANDA approvals.

2. *MDRP*

"In 1990, Congress created the Medicaid [D]rug [R]ebate [P]rogram . . . to offset Medicaid costs incurred by the federal government and the states for outpatient drugs provided to Medicaid recipients." *Council on Radionuclides & Radiopharmaceuticals, Inc. v. Azar*, No. 18-633, 2019 WL 5960142, at *2 (D.D.C. Nov. 13, 2019); *see also Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 114 (2011). The MDRP statute, enacted as part of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388, provides that drug manufacturers must enter into rebate agreements with the Department of Health and Human Services and must agree to pay rebates to the states in order to receive state Medicaid payments for covered outpatient drugs. 42 U.S.C. § 1396r-8(a). It also sets forth the terms for such rebate agreements. *Id.* § 1396r-8(b); *Pharm. Research & Mfrs. v. Walsh*, 538 U.S. 644, 652 (2003).

The statute establishes rebate rates for three different categories of drugs: (1) single source, (2) innovator multiple source, and (3) noninnovator multiple source. 42 U.S.C. § 1396r-8(c); *id.* § 1396r-8(k)(7)(A). It requires drug manufacturers to pay higher rebate rates to the states for drugs falling into the first and second categories than for those falling into the third category. *Compare* 42 U.S.C. § 1396r-8(c)(1) & (2) *with id.* § 1396r-8(c)(3); *see also Medicaid Program; Covered Outpatient Drugs*, 81 Fed. Reg. 5,170, 5,196 (Feb. 1, 2016) ("The statute requires a different rebate formula for single source and innovator multiple source drugs, which results in higher rebates owed for those drugs than for noninnovator multiple source drugs."). Drug manufacturers are required to self-report to CMS regarding the proper classification of the covered drugs that they market, *see id.* § 1396r-8(b)(3), and may be penalized for misreporting the classification, *id.* § 1396r-8(b)(3)(C)(iii)(I); *see also U.S. ex rel. Conrad v. GRIFOLS Biologicals Inc.*, No. 07-3176, 2010 WL 2733321, at *2 (D. Md. July 9, 2010) (discussing a

claim under the False Claims Act "alleg[ing] that Defendants knowingly and falsely classified their pharmaceutical products as noninnovators rather than innovators in order to reduce their quarterly rebate costs").

Although Congress amended the MDRP statute in relevant respects in 2019, *see* Medicaid Services Investment and Accountability Act of 2019, Pub. L. No. 116-16, 133 Stat. 852 § 6(c), all agree that the prior version of statute—which went unchanged in relevant respects from its enactment in 1990 until the recent amendments in 2019—governs the present dispute. *Compare* 42 U.S.C. § 1396r-8 (2012 version) *with id.* § 1396r-8 (1990 version); *see also* Dkt. 15-1 at 27 (listing definitions from earlier version of the statute); Dkt. 17 at 8–9 (same). Under that earlier version of the statute, a "single source drug" was defined as "a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration." 42 U.S.C. § 1396r-8(k)(7)(A)(iv) (2012 version). A "multiple source drug" was defined as "a covered outpatient drug . . . for which there [is] at least 1 other drug product which—(I) is rated as therapeutically equivalent . . . (II) . . . is pharmaceutically equivalent and bioequivalent . . . and (III) is sold or marketed in the United States during the period." *Id.* § 1396r-8(k)(7)(A)(i). An "innovator multiple source" drug was "a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration." *Id.* § 1396r-8(k)(7)(A)(ii). And a "noninnovator multiple source" drug was defined as "a multiple source drug that is not an innovator multiple source drug." *Id.* § 1396r-8(k)(7)(A)(iii).

Over the years, the agencies responsible for interpreting and administering the MDRP statute have issued numerous notices of proposed rulemakings and finalized rules construing the MDRP statute and its drug categories. In 1995, the Health Care Financing Administration

("HCFA"), CMS's predecessor agency, published a proposed rule acknowledging that no relevant statute "define[s] the term 'original NDA,'" as that term was used in the definitions of "single source" and "innovator multiple source" drugs. *Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers*, 60 Fed. Reg. 48,442, 48,453 (Sept. 19, 1995) (proposed rule). HCFA proposed to "interpret [the term] to comport with [the agency's] understanding of the intent of the Congress" and, thus, to mean an "FDA-approved drug or biological application that received one or more forms of patent protection . . . or marketing exclusivity rights granted by the FDA." *Id.* The notice of proposed rulemaking continued:

> Based on the statute, which requires larger rebates for single source and innovator multiple source drugs, we believe the term "original NDA" was included in [§§] 1927(k)(7)(A)(ii) and (iv) of the Act for the purposes of extracting larger rebates from those products that received some form of patent or marketing protection for a specific period of time . . . than noninnovators that produce generic drugs with no market protection. We believe the term "original NDA," as proposed above, produces this effect.

Id. The proposed rule would have defined a "noninnovator multiple source" drug to include "[a]ll products approved under an abbreviated new drug application, [or a] *paper new drug application under the FDA's former "Paper NDA" policy* . . . ." *Id.* at 48,482 (emphasis added).

The proposed rule, however, was never finalized.[3] Instead, nearly thirteen years later, in 2007, CMS published a final rule that addressed the definition of an "innovator multiple source" drug. CMS noted:

> By statute, an innovator multiple source drug is a drug that was originally marketed under an original NDA approved by the FDA. We do not believe that

[3] In 2007, CMS explained that, "[d]ue to the time that has elapsed since the publication of the 1995 proposed rule and changes in the prescription drug industry, [it did] not plan to finalize [certain] provisions of that proposed rule, and any comments on the 1995 proposed rule are outside the scope of this final rule with comment period." *Medicaid Program; Prescription Drugs*, 72 Fed. Reg. 39,142, 39,143 (July 17, 2007).

> it would be consistent with the statute to modify the definition to include drugs marketed under an ANDA. To clarify the distinction between multiple source drugs approved under an ANDA and multiple source drugs approved under an NDA, we are adding a definition of noninnovator multiple source drug in this final rule. Noninnovator multiple source drugs are defined as multiple source drugs marketed under an ANDA or an abbreviated antibiotic drug application.
>
> In response to comments regarding drugs that entered the market prior to 1962, we believe these drugs are not classified as innovator multiple source drugs unless they are marketed under an NDA. Further, we recognize the need to classify drugs that entered the market prior to 1962 that are not marketed under an NDA. Therefore, we are further defining noninnovator multiple source drugs as drugs that entered the market prior to 1962 that were not originally marketed under an original NDA.

Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,162 (Jul. 17, 2007) (final rule). CMS also responded to two comments asking that it define the terms "NDA" and "original NDA." CMS explained: "We do not see the need to add a definition of NDA in this final rule. Further, the FDA does not make a distinction between an NDA and an original NDA; therefore, we view these terms as having the same meaning." *Id.* at 39,163.

In February 2012, CMS published a proposed rule in which it acknowledged that "questions have arisen regarding whether an 'original NDA' is the same as an NDA and whether the drug category may be different if a drug is approved under an NDA." *Medicaid Program; Covered Outpatient Drugs*, 77 Fed. Reg. 5,318, 5,323 (Feb. 2, 2012). CMS "propos[ed] to clarify that, for the purposes of the [MDRP], an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness," which is to say, not an ANDA. *Id.* It went on, however, to state: "In light of this definition, we are proposing to use the term 'NDA' when addressing such application types for *brand name* drugs and not use the term 'original NDA' when referring to such drugs." *Id.* (emphasis added).

In its final rule, published in February 2016, CMS asserted: "As currently defined . . . an innovator multiple source drug means a multiple source drug that was originally marketed under an original NDA approved by FDA, including an authorized generic drug."[4] *Medicaid Program; Covered Outpatient Drugs*, 81 Fed. Reg. 5,170, 5,190 (Feb. 1, 2016). CMS summarized various comments that had taken issue with CMS's stated intention to read "original NDA" as the equivalent of "NDA" and that had pointed out the effects that this construction might have on generics that were approved under NDAs. *Id.* at 5,191. CMS then clarified its definitions of the three drug categories. According to CMS, an "innovator multiple source" drug was

> a drug that was initially marketed under an NDA, other than an ANDA, approved by FDA but is rated therapeutically equivalent to at least one other product in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) that is sold or marketed in the United States during the rebate period.

Id. CMS further explained that "the Act defines noninnovator multiple source drugs as multiple source drugs that are not innovator multiple source drugs, which are *typically* marketed under an ANDA, as opposed to an NDA, approved by FDA" and that the "term 'original NDA' is designed *typically* to mean an NDA (including an NDA filed under [§] 505(b)(1) or (2) of the FFDCA), other than an ANDA, which is approved by the FDA for marketing." *Id.* (emphasis added). But CMS acknowledged some exceptions to this general pronouncement:

> There may be very limited circumstances where, for the purposes of the [MDRP], certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug. For example, . . . certain drugs approved under a paper NDA prior to the enactment of the Hatch-Waxman Amendments of 1984 or under certain types of literature-based [§] 505(b)(2) NDA approvals after the Hatch-Waxman

[4] An "authorized generic drug" is a generic duplicate drug produced by the same manufacturer that gained FDA approval of the NDA for the "branded" drug that the generic replicates. *See* FTC, *Authorized Generic Drugs: Short–Term Effects and LongTerm Impact* i–ii (2011), available at http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf; *see also Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005).

> Amendments of 1984 might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug, depending on the unique facts and circumstances of the particular situation.

Id. These drugs, according to CMS, fell into "very narrow exceptions to the rule that drugs marketed under NDAs . . . , other than ANDAs, should be classified as either single source or innovator multiple source drugs." *Id.* It cautioned that "the narrow exception will not be considered applicable to drugs marketed under NDAs that were not approved under . . . the paper NDA process prior to 1984" or in other specific circumstances. *Id.*

On May 2, 2016, CMS circulated a Medicaid Rebate Program Notice for Participating Drug Manufacturers, which explained the Final Rule's "narrow exception" and informed drug manufacturers how they could go about securing CMS's approval allowing their drugs to be classified as noninnovator multiple source drugs. AR 88. "Certain drugs approved under a paper NDA prior to enactment of the Hatch-Waxman Amendments of 1984" appeared in the Notice's list of three "examples of drugs with NDA approvals which might be more appropriately treated as if they were approved under an ANDA and classified as noninnovator multiple source drugs." AR 88–89. The Notice explained that drug manufacturers that wanted their drugs treated under this "narrow exception" should submit to CMS certain supporting information, which could include "[i]nformation that indicates the drug never received patent protection or market exclusivity;" "[i]nformation about the reference drug, if any, that may have been used for the approval of the drug for which the manufacturer is seeking the narrow exception;" and "[i]nformation about past or current therapeutic equivalents, if any, for the drug." AR 89.

B. Plaintiff STI Pharma and Sulfatrim Pediatric Suspension

STI Pharma markets Sulfatrim, a drug that gained FDA approval through the paper NDA approval process in 1983 based on its equivalence to Bactrim Suspension. *See* AR 58, 72, 74, 77. Bactrim Suspension, in turn, was approved pursuant to an NDA years earlier. *See* AR 10. A different company owned the rights to Sulfatrim at the time the FDA approved the drug. *See* AR 74; Product Details for NDA 017560 Bactrim (Sulfamethoxazole; Trimethoprim); Orange Book: Approved Drug Products with Therapeutic Equivalents Evaluations, FDA, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=017560#1754 (last visited March 22, 2020) (noting that Bactrim was approved before January 1, 1982). Plaintiff purchased the right to market Sulfatrim in 2011 from Actavis Mid Atlantic, LLC ("Actavis"). AR 12. During the period that Actavis marketed Sulfatrim, it categorized the drug as a noninnovator multiple source drug. *Id.*

STI Pharma began to market Sulfatrim in 2013. AR 12. It submitted the statutorily required information about Sulfatrim to CMS and, unlike Actavis, categorized the drug as an innovator multiple source drug. *Id.* As a result, STI Pharma paid rebates to the states at the higher rate that corresponded to innovator multiple source drugs and single source drugs. *See* 81 Fed. Reg. at 5,196. In February 2016, following the publication of CMS's 2016 final rule, STI Pharma asked CMS to reclassify Sulfatrim as a noninnovator multiple source drug under the "narrow exception" for duplicate drugs originally approved under paper NDAs. AR 64–68. CMS granted that request prospectively, effective April 1, 2016. AR 61.

Several months later, STI Pharma requested CMS's permission to apply Sulfatrim's new noninnovator multiple source drug status retroactively to the fourth quarter of 2013, when Plaintiff first began marketing Sulfatrim, through the first quarter of 2016, when the 2016 final

rule took effect. AR 56. STI Pharma represented that it had reported Sulfatrim to CMS as an innovator multiple source drug in error. AR 58 (stating that STI Pharma did so "mistakenly"); AR 64 (stating that STI Pharma did so "in accordance with STI's understanding of CMS's position during this period"). On August 23, 2017, CMS denied Plaintiff's request because "the reporting of Sulfatrim as an [innovator] drug for the period [in question] was correct." AR 47. CMS explained that "[t]he Final Rule, which was . . . effective April 1, 2016, established the narrow exception process to address the limited circumstances where drugs approved under an NDA might be more appropriately treated as if they were approved under an ANDA and classified as noninnovator multiple source drugs." *Id.* CMS would apply this change only prospectively because "[a] drug category change pursuant to a narrow exception request approval does not apply to reporting periods prior to the effective date of the Final Rule because the narrow exception did not exist before that date." *Id.*

In response, STI Pharma requested that CMS reconsider its decision, AR 24, 39, and, in December 2017, the company requested a meeting with CMS officials, AR 36. That meeting occurred in early 2018. *Id.* Days after the meeting, STI Pharma told CMS that it planned to recalculate the rebates it owed the states for the disputed period to reflect that Sulfatrim was noninnovator, and not an innovator, multiple source drug. AR 33. The company also indicated that it planned to request that the states reimburse it for what it believed to be overpayments due to the alleged misclassification during that period. *Id.* CMS maintained its position regarding the proper categorization of Sulfatrim for the 2013–2016 period and told STI Pharma that it would alert the states that they should carefully review the company's submissions in order to detect any underpayments based on the company's theory that it was entitled to retroactive recategorization. *See* AR 31–32.

On May 25, 2018, Plaintiff initiated this action. Dkt. 1. It claims that CMS's refusal to correct Sulfatrim's drug classification for the fourth quarter of 2013 to the first quarter of 2016 was arbitrary, capricious, and not in accordance with law (1) because it exceeded the agency's authority, and (2) because the agency's action is unsupported by, and lacks a rational connection to, the evidence in the administrative record. *See id.* at 14–15 (Compl. ¶¶ 43–51). It seeks declaratory, mandamus, and injunctive relief requiring CMS to "take prompt action to correct its records to reflect Sulfatrim's [noninnovator] drug status" from the fourth quarter of 2013 to the first quarter of 2016 and to "inform state Medicaid agencies of this action." *Id.* at 16. CMS filed the administrative record, Dkt. 14, and the parties subsequently cross-moved for summary judgment, Dkt. 15; Dkt. 17.

Because neither party addressed the Court's jurisdiction, the Court ordered the parties to "file . . . short briefs or declarations discussing the basis for STI Pharma's standing to sue" and explaining the mechanisms through which a favorable outcome for Plaintiff would redress the alleged financial injury it suffered. Minute Order (Mar. 9, 2020). On March 18, 2020, the parties submitted supplemental filings addressing STI Pharma's standing. Dkt. 24; Dkt. 25.

II. LEGAL STANDARD

"[W]hen a party seeks review of agency action under the APA . . . [t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "[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." *New Lifecare Hosps. of Chester Cty. LLC v. Azar*, 417 F. Supp. 3d 31, 41 (D.D.C. 2019) (quoting *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006)). The Court will grant summary judgment to the agency if it did not "violate[] the Administrative Procedure Act by taking action

that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Deppenbrook v. Pension Benefit Guar. Corp.*, 778 F.3d 166, 171 (D.C. Cir. 2015) (quoting 5 U.S.C. § 706(2)). In instances in which there is no factual dispute, the Court's "analysis is limited to the validity of the FDA's interpretation and application of the statute." *AstraZeneca Pharm. LP v. FDA*, 713 F.3d 1134, 1139 (D.C. Cir. 2013).

III. ANALYSIS

A. Subject-Matter Jurisdiction

Although not raised by the parties, the Court has an independent duty to ensure that it has subject-matter jurisdiction. *See Obaydullah v. Obama*, 688 F.3d 784, 788 (D.C. Cir. 2012). "Because standing is an element of the [Article III] case or controversy requirement, a court does not have subject matter jurisdiction if a plaintiff lacks standing." *Gulf Restoration Network, Inc. v. Nat'l Marine Fisheries, Serv.*, 730 F. Supp. 2d 157, 165 (D.D.C. 2010) (citing *In re Navy Chaplaincy*, 534 F.3d 756, 759 (D.C. Cir. 2008)). Here, the Court requested that the parties provide supplemental filings explaining the basis for STI Pharma's standing and, in particular, addressing the question how the relief requested in this matter—in effect, recategorization dating back to 2013—would redress STI Pharma's alleged injury. Minute Order (Mar. 9, 2020).

The parties agree that STI Pharma has standing to sue and explained that, if the company prevails, CMS will allow it to "change its drug category retroactively," and "CMS would then update the drug category in its drug data reporting database . . . , recalculate the unit rebate amount ('URA') for Sulfratrim, and disseminate the updated URA for Sulfatrim to the states." Dkt. 24 at 2; *see also* Dkt. 25 at 2–3. The states then "reconcile [any rebate] overpayments with the drug manufacturer" and can "issue a credit upon agreement with the manufacturers about where the manufacturer would like the credit applied." Dkt. 24 at 2–3 (second quote quoting 83

Fed. Reg. 12,770, 12,776 (Mar. 23, 2018)). Given this scheme, the Court is satisfied that STI Pharma has standing to sue because "a favorable decision would create 'a significant increase in the likelihood that [it] would obtain relief that directly redresses the injury suffered.'" *Klamath Water Users Ass'n v. FERC*, 534 F.3d 735, 739 (D.C. Cir. 2008) (quoting *Utah v. Evans*, 536 U.S. 452, 464 (2002)).

B. Merits

The parties agree in their opening briefs that the familiar framework set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), governs the present dispute. *See* Dkt. 15-1 at 28; Dkt. 17 at 21 ("The parties agree that the Chevron framework applies to CMS's action in this case."). In its reply brief, however, STI Pharma vacillates between its original position that *Chevron* applies, Dkt. 19 at 9 ("When analyzed properly under the familiar framework of *Chevron* . . . ."), and the view that *Chevron* is inapposite "because CMS's interpretation was announced in a letter to STI", *id.* at 17 (citing *United States v. Mead Corp.*, 533 U.S. 218, 299 (2001)). Defendant's response to Plaintiff's equivocal filing maintains that *Chevron* governs. *See* Dkt. 21 at 4 ("*Chevron* deference therefore applies to CMS's reasonable interpretation of the statute."). Ultimately, this disagreement—if there is one—is beside the point because the case can and must be decided at *Chevron* step one, and there is no difference between the *Chevron* step one analysis and the analysis the Court would employ in the absence of an administrative interpretation of the statute.

Under *Chevron* step one, the Court must first determine "whether Congress has directly spoken to the precise question at issue." *Chevron U.S.A. Inc.*, 467 U.S. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. It is only "[i]f the

statutory provision in question is 'silent or ambiguous with respect to the specific issue,'" that the Court must proceed to *Chevron* step two and "determine whether [the agency's] interpretation is 'based on a permissible construction of the statute.'" *Nat'l Envtl. Dev. Ass'ns Clean Air v. EPA*, 891 F.3d 1041, 1047 (D.C. Cir. 2018) (quoting *Chevron*, 467 U.S. at 843). This case begins and ends with *Chevron* step one.

"[T]he judiciary," as *Chevron* explains, "is the final authority on issues of statutory construction," and, as a result, deference does not come into play until after the Court has exhausted "the traditional tools of statutory interpretation" to determine whether "Congress had an intention on the precise question at issue." *Chevron*, 467 U.S. at 843 n.9. "[O]nly when that legal toolkit is empty and the interpretative question still has no single right answer can a judge conclude that" the issue in dispute "is 'more [one] of policy than of law.'" *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (internal citation omitted) (addressing *Auer* deference). In other words, the Court must consider "the text, structure, history, and purpose" of the statute "in all the ways it would" have done had the case come before it without the backstop of the agency's interpretation. *Id.*; *see also Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004) ("[D]eference to [an agency's] statutory interpretation is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent."); *Mozilla Corp. v. FCC*, 940 F.3d 1, 20 (D.C. Cir. 2019) ("[W]e do not apply *Chevron* reflexively, and we find ambiguity only after exhausting ordinary tools of judicial craft."); *Fin. Planning. Assoc. v. SEC*, 482 F.3d 481, 487 (D.C. Cir. 2007) (court must consider the "overall statutory scheme, as well as the problem Congress sought to solve"). If those tools yield a single correct interpretation of the statute, that ends the matter. *Chevron*, 467 U.S. at 842.

The question of statutory interpretation presented here is whether the pre-2019 version of the MDRP statute answers the question whether a duplicate drug marketed pursuant to a pre-Hatch-Waxman paper NDA constituted an "innovator multiple source" or a "noninnovator multiple source" drug. That is not how CMS would frame the issue; it argues, instead, that "[t]he precise question here is whether Congress unmistakably intended drugs approved under the paper NDA approval process to be categorized as noninnovator multiple source drugs." Dkt. 17 at 23. But that formulation misunderstands *Chevron* and the role of judiciary in statutory interpretation. *Chevron* does not impose an "unmistakability" test but, rather, asks whether "the text, structure, history, and purpose" of the statute offer a judicially-discernible answer to the question posed, or whether, instead, Congress explicitly or implicitly left it to the agency to decide. *See Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) (explaining that courts must "exhaust the traditional tools of statutory construction" before deferring to the agency's reasonable interpretation); *Catawba Cty. N.C. v. EPA*, 571 F.3d 20, 32–33 (D.C. Cir. 2009) (analyzing statutory text and structure and concluding that "the intent of Congress is clear"); *Chevron*, 467 U.S. at 843–44 (discussing explicit or implicit delegations to the agency). If the Court determines "that the governing statute, read 'as a whole', reveal[s] a clear congressional intent regarding the relevant question," or that "the text [of the statute] and reasonable inferences from it give a clear answer," then the final word on the meaning of the statute is for the courts, and not the agency. *Nat'l Envtl. Dev. Ass'ns Clean Air*, 891 F.3d at 1048 (internal citations omitted).

In addressing a question of statutory interpretation, the Court begins with the text of the statute during the relevant period. *See City of Clarksville v. FERC*, 888 F.3d 477, 482 (D.C. Cir. 2018). Here, the MDRP statute identified three categories of drugs: (1) "single source drug[s],"

(2) "innovator multiple source drug[s]," and (3) "noninnovator multiple source drug[s]."[5] 42 U.S.C. § 1396r-8(k)(7)(A) (2012 version). A "multiple source drug" was a drug "for which there [is] at least 1 other drug product which" is equivalent in defined respects. *Id.* § 1396r-8(k)(7)(A)(i). A "[s]ingle source drug" was a drug marketed "under an original new drug application approved by the" FDA. *Id.* § 1396r-8(k)(7)(A)(iv). An "[i]nnovator multiple source drug" was a "multiple source drug that was originally markets under an original new drug application approved by the" FDA. *Id.* § 1396r-8(k)(7)(A)(ii). And, a "[n]oninnovator multiple source drug" was a "multiple source drug that is not an innovator multiple source drug." *Id.* § 1396r-8(k)(7)(A)(iii). According to STI Pharma, Sulfatrim was a "noninnovator multiple source drug" because the FDA approved the drug based on its equivalence to Bactrim Suspension and because the FDA approved the NDA for Bactrim Suspension before it approved the paper NDA for Sulfatrim. Dkt. 15-1 at 21, 31. In other words, Sulfatrim and Bactrim Suspension are equivalent drugs, and the "original" NDA was granted for Bactrim Suspension—not Sulfatrim. CMS agrees that this is a permissible reading of the MDRP statute, and, indeed, that is the interpretation CMS itself adopted in the 2016 Rule. 81 Fed. Reg. at 5,191 (allowing for duplicate drugs authorized through the paper NDA process to be categorized as noninnovators). But, in the agency's view, this is not the only permissible reading of the statute, and because the statute was ambiguous, it was entitled to—and did in fact—adopt a contrary reading prior to 2016.[6]

[5] Because the 2019 amendment to the statute has no bearing on this case, the Court will cite to and discuss the pre-2019 version of the statute for the remainder of this opinion.

[6] It is far from clear that CMS did, in fact, adopt a contrary reading of the statute before 2016, but, given the Court's conclusion of the plain meaning of the statute, the Court need not reach that separate question.

Two statutory terms inform STI Pharma's argument—"original NDA" and "innovator." In its view, it does not hold the "original NDA" for the drug, and Sulfatrim was not an "innovator" drug. Because neither of these terms were defined in the statute, the Court must "start with the assumption that the legislative purpose is expressed by the ordinary meaning of the words used." *Russello v. United States*, 464 U.S. 16, 21 (1983) (quoting *Richards v. United States*, 369 U.S. 1, 9 (1962)). As STI Pharma notes, the dictionary defines the term "original" to mean "not secondary, derivative, or imitative" and "being the first instance or source from which a copy, reproduction, or translation is or can be made." Dkt. 19 at 11 (quoting Merriam-Webster's Collegiate Dictionary, 10th Ed. (1994)); *see also* Original, Merriam-Webster's Third New International Dictionary (1993) ("original" defined as "constituting a source, beginning, or first reliance" and "constituting the product or model from which copies are made"). Under that definition, the paper NDA for Sulfatrim was not an "original" NDA.

The FDA approved Sulfatrim as a duplicate of Bactrim. The documents pertaining to its approval, which are contained in the administrative record, repeatedly refer to Sulfatrim as a "generic version of the Bactrim product," AR 74, and state that its approval was as a "duplicate NDA for a post 1962 drug [Bactrim]," AR 76; *see also* AR 80 (referring to Bactrim as the "reference drug"); AR 81 ("The reference drug will be B[actrim] S[uspension] containing the same amounts of active ingredient per 5 ml."). In other words, Sulfatrim was not the "source," "beginning," or "the product or model from which copies are made." *See* Original, Merriam-Webster's Third New International Dictionary (1993). Rather, Bactrim was.

CMS makes two points in response. First, it argues that

> [b]y using "original" as an adjective, Congress made plain that it intended to differentiate between types of new drug applications. Congress also identified two types of new drug applications in its definition of "covered outpatient drug,"

> NDAs (under [§] 505(b) of the FFDCA) and abbreviated NDAs (under section 505(j) of the FFDCA).

Dkt. 17 at 24 (citing 42 U.S.C. § 1396r-8(k)(2)(A)(i)). CMS posits that Congress might have used the term "original" to invoke the distinction made in the definition of "covered outpatient drugs," 42 U.S.C. § 1396r-8(k)(2)(A)(i), between drugs approved under the NDA provision of the FFDCA, 21 U.S.C. § 355, and those approved under the ANDA provision, *id.* § 355(j). The Court is unconvinced.

To begin, "when 'Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'" *United States v. Papagno*, 639 F.3d 1093, 1099 (D.C. Cir. 2011) (quoting *Kucana v. Holder*, 558 U.S. 233, 249 (2010)). Congress used the comparatively broad phrase "original new drug application" in defining "innovator multiple source drug;" it did not reference what CMS characterizes as the "two types of new drug applications in its definition of 'covered outpatient drug.'" Dkt. 17 at 24 (quoting 1396r-8(k)(2)(A)(i)). In defining "covered outpatient drugs" in the same statute, Congress demonstrated that it knew how to reference 21 U.S.C. § 355 (NDAs) and 21 U.S.C. § 355(j) (ANDAs) when it so chose. *See* 42 U.S.C. § 1396r-8(k)(2)(A)(i). Even more to the point, the statutory definition of "covered outpatient drugs" did not distinguish among or classify drugs in the manner CMS suggests; rather, the definition collected all the various ways that drugs were lawfully marketed, whether pursuant to an NDA, an ANDA, or a pre-1962 procedure. *Id.* § 1396r-8(k)(2)(A). To be sure, the FFDCA did distinguish between NDAs and ANDAs. But that distinction did not equate NDAs with "original NDAs" and ANDAs with non-original NDAs. Had Congress intended to draw the distinction between NDAs and ANDAs that CMS suggests, it could easily have defined an "noninnovator multiple source drug" to mean a drug

marketed under an ANDA. That fact that Congress did not use this well-established nomenclature speaks volumes.

Second, CMS notes that the dictionary also defines the term "original" to mean "initial," Dkt. 17 at 25 (citing Merriam-Webster Dictionary (2019)). CMS argues:

> An NDA approved under section 505(b) is the initial drug application for any new drug . . . . An [ANDA] under section 505(j) is not an original NDA because it is not the initial NDA. Accordingly, using "original" to distinguish between those two approval processes is consistent with the dictionary definition of "original."

Dkt 17 at 25. CMS goes on to assert that, "[b]efore 1984, Congress recognized only one NDA approval process, the one set forth under 505(b)" and that, by creating modern ANDAs, the Hatch-Waxman Amendments created a new, non-initial type of application. *Id.* at 25–26. From this, CMS again contends that Congress might have used the word "original" to distinguish between NDAs and ANDAs. The Court is, again, unpersuaded.

CMS's first premise is a sound one. The current version of the FFDCA recognizes two forms of new drug applications—NDAs, which typically require the manufacturer to conduct extensive studies and trials to prove the safety and effectiveness of the new drug, and ANDAs, which piggyback on the a previously approved NDA and require the manufacturer to demonstrate only equivalence and to meet various labeling, chemistry, manufacturing, and packaging requirements. *See Amneal Pharms. LLC v. FDA*, 285 F. Supp. 3d 328, 333 (D.D.C. 2018). It is thus true, as a matter of logic, that an ANDA can never be an "original" NDA, and it is true, as a matter of economics and common practice, that since Congress enacted the Hatch-Waxman Amendments in 1984, NDAs are invariably the "original" new drug applications for drugs containing active ingredients not included in a previously approved drug. *See* 21 U.S.C. § 355(j).

But that is as far as the logic of CMS's argument runs. The problem is as follows: Even if *all* NDAs were "initial" or "original" new drug applications, and even if *no* ANDAs were "initial" or "original" new drug applications, those premises have no bearing on STI Pharma's commonsense contention that the paper NDA for Sulfatrim was not the "original" new drug application for that drug. To use an analogy, it is true that all dogs are mammals and that no birds are mammals. But those premises tell us nothing about whether insects are mammals. By the same token, CMS's description of NDAs and ANDAs tells us nothing about whether pre-Hatch-Waxman paper NDAs were new drug applications. What matters is that a paper NDA for a duplicate drug, like Sulfatrim, could not be approved without making reference to a previously approved—or "original"—new drug application. *See Response to Petition Seeking Withdrawal of the Policy Described in the Agency's "Paper" NDA Memorandum of July 31, 1978*, 45 Fed. Reg. 82,052, 82,053, 83,057 (Dec. 12, 1980) (noting that the application for the first approved duplicate paper NDA "was submitted on April 21, 1977," long after drug manufacturers were first required to prove safety and effectiveness through NDAs). In other words, Sulfatrim was not—and could not have been—marketed under "an original new drug application." It was marketed under a follow-on application, much like a drug approved under an ANDA.

The MDRP statute's use of the word "innovator" further confirms that Congress intended to distinguish between pioneer drugs, like most drugs approved under the post-Hatch-Waxman NDA process, and follow-on drugs, like ANDAs and paper NDAs for duplicate drugs. The dictionary defines the verb "innovate" as "to introduce as or as if new." Merriam-Webster's Collegiate Dictionary, (10th ed.1994). Courts have used the word "innovator" interchangeably with the word "pioneer" in referring to novel, non-generic drugs. *See Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1494–95 (D.C. Cir. 1996); *AstraZeneca Pharm. v. FDA*, 850 F. Supp.

2d at 233 (D.D.C. 2012) ("In the United States, new drugs, including 'generic' versions of previously approved 'pioneer' or 'innovator' drugs, may not be marketed without the FDA's approval."). The dictionary, in turn, defines the adjective "pioneer" as "original, earliest." Pioneer, *Merriam-Webster.com Dictionary*, Merriam-Webster, https://www.merriam-webster.com/dictionary/pioneer (last accessed Mar. 21, 2020). As STI Pharma notes, this common understanding of the word "innovator" shows "that Congress did not intend to classify *duplicate* generic drugs as *innovator* multiple source drugs." Dkt. 15-1 at 31 (emphasis added). CMS's reading of the statute, in contrast, would require the Court to construe the phrase "innovator drugs" to have included drugs, like Sulfatrim, that the FDA approved as "generic version[s] of" drugs previously approved, AR 74, based on "duplicate NDA[s]," AR 76, relying on studies conducted using the "reference drug," AR 81.

CMS responds that the Court should not look to the dictionary definition of "innovate" because Congress itself defined the phrase "innovator multiple source drug." Dkt. 17 at 26. It asserts that only where a word has not been "otherwise defined" in the statute should courts look to the word's ordinary meaning. *Id.* (citing *Perrin v. United States*, 444 U.S. 37, 42 (1979)). That is incorrect. As the Supreme Court has observed, "[i]n settling on a fair reading of a statute, it is not unusual to consider the ordinary meaning of a defined term." *Bond v. United States*, 572 U.S. 844, 861 (2014). In *Bond v. United States*, for example, the Court considered the ordinary meaning of the defined term "chemical weapon" in rejecting an interpretation of its definition that "would sweep in everything from the detergent under the kitchen sink to the stain remover in the laundry room." *Id.* at 862; *see also Johnson v. United States*, 559 U.S. 133, 140 (2010) (looking to the ordinary meaning of the defined statutory term "violent felony" to aid in interpretation of the statute). To be sure, had Congress defined the term "innovator drug" to

mean the first, second, and third version of the same drug approved by the FDA, CMS would have a point, and the Court would not be free to give the word "innovator" its well-accepted meaning. But that is far from what Congress did here. To the contrary, it defined the term to refer to the "*original* new drug application," and it is CMS—and not STI Pharma—that resists the ordinary meaning of that statutory definition.

Finally, STI Pharma's reading of the statute—and, for that matter, CMS's prospective reading of the statute—is most consistent with the statutory purpose. Congress enacted the MDRP statute in 1990 "to offset Medicaid costs incurred by the federal government and the states for outpatient drugs provided to Medicaid recipients." *Council on Radionuclides*, 2019 WL 5960142, at *2. "Low-cost generic drugs" presented less of a financial problem than did higher cost novel drugs still benefiting from the marketing exclusivity provided by the Hatch-Waxman Amendments. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *see also TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (2003) (noting that patent owners' "valuable rights in the pioneer drug could be threatened by the marketing of cheaper, generic versions of their patented innovations"); *Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) (noting the "greater affordability" of generic drugs). The difference in the rebate rates for "single source" and "innovator multiple source drugs" as compared to "noninnovator multiple source drugs" reflects that reality. *See GRIFOLS Biologicals Inc.*, 2010 WL 2733321, at *2 ("Under the Rebate Program, CMS imposes larger rebate payments on manufacturers of innovators, which enjoy exclusivity in the market for a period of time, than on manufacturers of noninnovators, which do not benefit from such exclusivity." (internal quotations and citations omitted). Innovator drugs typically demand higher prices and place a disproportionate burden on the Medicaid program, and it makes sense that Congress intended to alleviate that burden by

requiring a higher rebate rate for innovator drugs. It makes no sense, in contrast, to treat manufacturers of drugs approved pursuant to ANDAs more favorably than those of drugs approved pursuant to paper NDAs for duplicate drugs.

Although the proposed rule was never finalized, this is just the understanding of the MDRP statute that HCFA articulated in the 1995, when it first considered implementing regulations. As HCFA explained:

> Based on the statute, which requires larger rebates for single source and innovator multiple source drugs, we believe the term "original NDA" was included in sections 1927(k)(7)(A)(ii) and (iv) of the Act for the purposes of extracting larger rebates from those products that received some form of patent or marketing protection for a specific period of time. This form of protection could have been achieved through either some type of patent on the drug or some type of marketing exclusivity rights granted by the FDA.
>
> . . . .
>
> Exclusivity rights can extend beyond the life of the patent and protect the manufacturer from competition in one or more specific market areas. Thus, the innovators of drug products with market protection often benefitted from a lack of competition and increased profits for a specific period of time. Therefore, innovators with market protection are required to pay larger rebates than noninnovators that produce generic drugs with no market protection. We believe the term "original NDA" . . . produces this effect.

60 Fed. Reg. at 48,453. This analysis may lack legal force, but it is both convincing and unrebutted by anything CMS now has to offer.

Finally, although the Court need not rely on the legislative history of the relevant version of the MDRP statute, particularly in light of the clarity of statutory text, that history confirms that Congress intended to draw a distinction between branded, innovator drugs and follow-on, generic drugs. According to the Explanatory Material Concerning Committee on Finance Reconciliation Submission Pursuant to House Concurrent Resolution 310, manufacturers of "non-innovator multiple-source" or "generic" drugs would be required to pay a rebate equal to a

set percentage "of the Average Manufacturer's Price (AMP)," while manufacturers of "single-source" or "patented" drugs and "innovatory multiple-source" or "brand-name" drugs with a "generic equivalent" would be required to pay a higher rebate. 101 Cong. Rec. 30,515 (daily ed. Oct. 18, 1990). In other words, the rebate was higher for patented and brand-name drugs and lower for generic drugs. Here, there is no dispute that Sulfatrim was approved by the FDA as "a generic version of the Bactrim product" that had already been approved by the FDA and marketed by its manufacturer. *See, e.g.*, AR 74.

* * *

For all of these reasons, the Court concludes that the version of the MDRP statute in effect during the relevant period is best read to treat duplicate drugs approved pursuant to paper NDAs as "noninnovator multisource drugs" subject to the lower rebate rate. Although CMS's arguments to the contrary are not frivolous, it is not the role of the Court to defer to an agency merely because it can make an argument or merely because the process of statutory interpretation requires some work. Rather, if the traditional tools of statutory interpretation—including the plain meaning of the text and the purpose of the statute—reveal a "single right answer" to the meaning of the statute, *Kisor*, 139 S. Ct. at 2415, that ends the matter. This is such a case. CMS's decision declining to reclassify Sulfatrim as a noninnovator multiple source drug for the period from 2013 through 2016 must be set aside as not in accordance with law. 5 U.S.C. § 706(2)(A).

CONCLUSION

For the foregoing reasons, the Court will **GRANT** Plaintiff's motion for summary judgment, Dkt. 15, **DENY** Defendant's cross-motion for summary judgment, Dkt. 17, and will **REMAND** the matter to CMS for further proceedings consistent with this opinion.

A separate order will issue.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: March 23, 2020