UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 18-633 (RBW)
ALEX M. AZAR II, in his official Capacity as Secretary of the United States Department of Health and Human Services, and	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Defendants.	)	

MEMORANDUM OPINION

The plaintiff, the Council on Radionuclides and Radiopharmaceuticals, Inc. (the "Council"), brings this civil action pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706 (2018), against the defendants, the United States Department of Health and Human Services (the "Department") and Alex Azar, in his official capacity as the Secretary of the Department (the "Secretary"), challenging the defendants' interpretation of certain provisions of the Social Security Act, 42 U.S.C. §§ 1396–1396w-5 (2018). See generally Complaint ("Compl."). Currently pending before the Court are the Plaintiff's Motion for Summary Judgment ("Pl.'s Mot.") and the Defendants' Cross-Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment ("Defs.' Mot."). Upon careful

consideration of the parties' submissions,[1] the Court concludes for the following reasons that it must deny the plaintiff's motion for summary judgment and grant the defendants' cross-motion for summary judgment.

I. BACKGROUND

Established in 1965 under Title XIX of the Social Security Act, the Medicaid program provides states with funding to provide medical assistance to individuals "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1. "In order to participate in the Medicaid program, a [s]tate must have a plan for medical assistance approved by the Secretary." Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 650 (2003) (citing 42 U.S.C. § 1396a(b)). A state's plan must, among other things, "define[] the categories of individuals eligible for benefits and the specific kinds of medical services that are covered" by the plan. Id. (citing 42 U.S.C. § 1396a(a)(10), (17)). And, a state may choose to provide, as part of its plan, payment under the Medicaid program for "covered outpatient drugs," see 42 U.S.C. § 1396a(a)(54), which are defined to include drugs that (1) "may be dispensed only upon prescription," 42 U.S.C. § 1396r-8(k)(2)(A); (2) are "approved for safety and effectiveness as a prescription drug," id. § 1396r-8(k)(2)(A)(i); and (3) are not "provided as part of, or as incident to and in the same setting as" certain specified services "and for which payment may be made . . . as part of payment for th[ose] [services] and not as direct reimbursement for the drug" (the "limiting definition"), id. § 1396r-8(k)(3).

[1] In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Defendants' Answer ("Defs.' Answer"); (2) the Memorandum of Points and Authorities in Support of Plaintiff's Motion for Summary Judgment ("Pl.'s Mem."); (3) the Memorandum in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment ("Defs.' Mem."); (4) the Plaintiff's Reply in Support of Motion for Summary Judgment and Opposition to Defendants' Cross-Motion for Summary Judgment ("Pl.'s Opp'n"); and (5) the Defendants' Reply to Plaintiff's Opposition to Defendants' Cross-Motion for Summary Judgment ("Defs.' Reply").

In 1990, Congress created the Medicaid drug rebate program (the "Medicaid Drug Rebate Program") to offset Medicaid costs incurred by the federal government and the states for outpatient drugs provided to Medicaid recipients. See Walsh, 538 U.S. at 652. Pursuant to the Medicaid Drug Rebate Program, a drug manufacturer, in order to receive state Medicaid payments for its covered outpatient drugs, must enter into a rebate agreement with the Secretary. See Pharm. Research & Mfrs. of Am. v. Thompson, 251 F.3d 219, 221 (D.C. Cir. 2001). The rebate agreement requires drug manufacturers to pay the state "a portion of the price of [its] drugs" for which payment is covered by a state under the Medicaid program. Id.; see 42 U.S.C. § 1396r-8(a), (b). The Medicaid Drug Rebate Program also requires that drug manufacturers, on a quarterly basis, submit, inter alia, drug pricing information, see id. § 1396r-8(b)(3)(A), and noncompliance with these reporting obligations subjects the drug manufacturer to monetary penalties, see id. § 1396r-8(b)(3)(C).

On February 1, 2016, the Centers for Medicare & Medicaid Services (the "CMS"), the division of the Department that administers the Medicaid program on behalf of the Secretary, issued a final rule revising the requirements "pertaining to [the] Medicaid reimbursement for covered outpatient drugs . . . [and] also revis[ing] other requirements related to [covered outpatient drugs], including key aspects of [their] Medicaid coverage and payment, and the [Medicaid] [D]rug [R]ebate [P]rogram" (the "Final Rule"). Joint Appendix ("JA") at 2. In its final rule, the CMS noted, in response to comments, that radiopharmaceuticals[2] "meet the definition of a [covered outpatient drug]," if they are approved by the United States Food and Drug Administration (the "FDA") as a "prescription drug," so long as the limiting provision does

[2] According to the Council, "[r]adiopharmaceuticals are used primarily as part of a variety of diagnostic imaging, and in some cases, therapeutic procedures," Compl. ¶ 30, and "are either themselves radioactive and/or used to produce radioactive 'patient ready' doses," id. ¶ 29.

not apply to the drug, id. at 7. CMS further stated that "radiopharmaceuticals[, including those used in compounding patient-ready doses,] qualify as a [covered outpatient drug] because of the approval process undergone with [the] FDA . . . [and] [t]herefore, radiopharmaceuticals are to be reported to the [Medicaid Drug Rebate] [P]rogram in the same manner as other [covered outpatient drugs] for the purposes of the administration of the [Medicaid Drug Rebate] [P]rogram." Id.

On March 19, 2018, the Council filed its complaint in this case, challenging the CMS's interpretation of the definition of "covered outpatient drugs" to include radiopharmaceuticals. See Compl. at 1. Thereafter, the parties filed their cross-motions for summary judgment, which are the subjects of this Memorandum Opinion.

II. STANDARD OF REVIEW

A moving party is entitled to summary judgment "if the movant 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). When ruling on a Rule 56(a) motion, the Court must view the evidence in the light most favorable to the non-moving party. See Holcomb v. Powell, 433 F.3d 889, 895 (D.C. Cir. 2006) (citing Reeves v. Sanderson Plumbing Prods., 530 U.S. 133, 150 (2000)). The Court must therefore draw "all justifiable inferences" in the non-moving party's favor and accept the non-moving party's evidence as true. Anderson v. Liberty Lobby Inc., 477 U.S. 242, 255 (1986). At the summary judgment stage, "[b]are allegations are insufficient," Sierra Club v. EPA, 292 F.3d 895, 898 (D.C. Cir. 2002). In responding to a motion for summary judgment, the non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Accordingly, the non-moving party must not rely on "mere

allegations or denials . . . but . . . must set forth specific facts showing that there [are] [ ] genuine issue[s] for trial." Anderson, 477 U.S. at 248 (second omission in original) (citation and internal quotation marks omitted). Thus, "[t]he mere existence of a scintilla of evidence in support of the [non-moving party's] position [is] insufficient" to withstand a motion for summary judgment, as "there must be [some] evidence on which the jury could reasonably find for the [non-movant]." Id. at 252.

III. ANALYSIS

The Court's analysis starts and ends "with the question of subject matter jurisdiction." Am. Freedom Law Ctr. v. Obama, 106 F. Supp. 3d 104, 108 (D.D.C. 2015) (Walton, J.) (quoting Aamer v. Obama, 742 F.3d 1023, 1028 (D.C. Cir. 2014)); see also NO Gas Pipeline v. FERC, 756 F.3d 764, 767 (D.C. Cir. 2014) ("It is fundamental to federal jurisprudence that Article III courts such as ours are courts of limited jurisdiction."). "Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.'" Susan B. Anthony List v. Driehaus, 573 U.S. 149, 157 (2014) (citing U.S. Const. art. III, § 2). "In an attempt to give meaning to Article III's case-or-controversy requirement, the courts have developed a series of principles termed 'justiciability doctrines,' among which are standing[,] ripeness, mootness, and the political question doctrine." Nat'l Treasury Emps. Union v. United States, 101 F.3d 1423, 1427 (D.C. Cir. 1996) (quoting Allen v. Wright, 468 U.S. 737, 750 (1984)). If a plaintiff lacks Article III standing, a district court

> need not delve into [a plaintiff's] myriad constitutional and statutory claims . . . because a court may not resolve contested questions of law when its jurisdiction is in doubt, as [h]ypothetical jurisdiction produces nothing more than a hypothetical judgment—which comes to the same thing as an advisory opinion, disapproved by [the Supreme] Court from the beginning.

Am. Freedom Law Ctr., 106 F. Supp. 3d at 108 (first, third, and fourth alterations in original)

(first quoting Crow Creek Sioux Tribe v. Brownlee, 331 F.3d 912, 915 (D.C. Cir. 2003); then quoting Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 101 (1998)).

> [T]he irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) "actual or imminent, not 'conjectural' or 'hypothetical.'" Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." Third, it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision."

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992) (second, third, fourth, and fifth alterations in original) (citations omitted). "An allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." Susan B. Anthony List, 573 U.S. at 158 (internal quotation marks omitted).

An association seeking to establish standing to sue on behalf of its members must further show that

> (1) at least one of its members would have standing to sue in his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires that an individual member of the association participate in the lawsuit.

Chamber of Commerce v. EPA, 642 F.3d 192, 199 (D.C. Cir. 2011) (quoting Sierra Club, 292 F.3d at 898). And, "it is not enough to aver that unidentified members have been injured," id. (citation omitted); instead, an association must provide "individual affidavits" from "members who have suffered the requisite harm," Summers v. Earth Island Inst., 555 U.S. 488, 499 (2009); see also Sierra Club, 292 F.3d at 899 (stating that the plaintiff "must set forth by affidavit or other evidence specific facts" to show it has standing).

The plaintiff, "[t]he party [that is] invoking federal jurisdiction[,] bears the burden of establishing standing," Clapper v. Amnesty Int'l USA, 568 U.S. 398, 411–12 (2013) (internal

quotations marks omitted), and "each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation," Susan B. Anthony List, 573 U.S. at 158 (internal quotations marks omitted). Therefore, "a plaintiff moving for summary judgment in [a] district court[] [ ] must support each element of its claim to standing 'by affidavit or other evidence.'" Sierra Club, 292 F.3d at 899 (quoting Lujan, 504 U.S. at 561).

The defendants argue that the Council "does not have standing because it has failed to establish that a single one of its members has suffered, or is likely to suffer, an injury traceable to [the] [d]efendants," and that they are therefore entitled to summary judgment. Defs.' Mem. at 2, 10.[3] The Council argues in response that the Final Rule not only "exposes [its] members to injuries that flow from the inability to report product and pricing data—the risk of civil penalties and enforcement, and the risks to product coverage," Pl.'s Opp'n at 6, but also "imposes, or would impose, significant costs upon [its] members, both member companies that already participate in the Medicaid [Drug] Rebate Program [(the 'participating members')] and member companies that do not participate in the Medicaid [Drug] Rebate Program currently [(the 'nonparticipating members')]," id. at 5. According to the Council, the Final Rule requires "[the participating] members [to] incur administrative costs associated with ongoing reporting of product data and processing rebate claims, as well as liability for the rebate amounts

[3] The defendants also argue that the "CMS's interpretation of the Medicaid Drug Rebate [Program] is reasonable and its explanation of that interpretation is neither arbitrary nor capricious." Defs.' Mem. at 2; see also Defs.' Mem. at 14–27. However, because the Court concludes that the Council lacks standing, the Court is precluded from determining the merits of these arguments. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 95 (1998) ("The requirement that jurisdiction be established as a threshold matter 'spring[s] from the nature and limits of the judicial power of the United States' and is 'inflexible and without exception.'" (alteration in original) (quoting Mansfield, C. & L.M.R. Co. v. Swan, 111 U.S. 379, 382 (1884)); see also NO Gas Pipeline, 756 F.3d at 767 ("It is fundamental to federal jurisprudence that Article III courts such as ours are courts of limited jurisdiction. Therefore, 'we must examine our authority to hear a case before we can determine the merits.'" (quoting Wyo. Outdoor Council v. U.S. Forest Serv., 165 F.3d 43, 47 (D.C. Cir. 1999))).

themselves," and "[the] nonparticipating members to participate in a government program that does not apply to them, at a significant price," id., including the costs associated with "hiring additional personnel; installing new information technology systems capable of evaluating, synthesizing, and collecting product information for reporting purposes; and training personnel in the requirements of the Medicaid [Drug] Rebate Program," id. at 6. However, the arguments advanced by the Council in its opposition to the defendants' summary judgment motion do not suffice to establish its standing because they are not supported by evidence, see Deloatch v. Harris Teeter, Inc., 797 F. Supp. 2d 48, 57 (D.D.C. 2011) (stating that "[t]he 'mere arguments of counsel . . . are not evidence' that may be used to defeat a motion for summary judgment." (quoting Barnette v. Ridge, No. Civ.A. 02-1897(RMC), 2004 WL 3257071, at *6 n.6 (D.D.C. Nov. 15, 2004)), and the Council has failed to submit evidence or identify any evidence already in the record establishing that at least one of its members has been harmed, or is likely to be harmed, as a result of the adoption of the Final Rule.[4]

The evidence submitted by the Council in support of its position that it has standing are declarations from two of its members, Curium US LLC ("Curium"), see Pl.'s Opp'n, Exhibit ("Ex.") A (Declaration of Dan Brague, CEO, Curium US LLC ("Curium Decl.")) ¶ 4, and Advance Accelerator Applications, see id., Ex. B (Declaration of Roger Estafanos of AAA ("AAA Decl.")) ¶ 4. However, contrary to the Council's assertion that these declarations "illustrat[e] that [its] members will suffer economic injury," Pl.'s Opp'n at 5, they are

[4] The Court notes that it reviewed two letters that were submitted by the parties in the Joint Appendix: one letter to the CMS from Mallinckrodt Pharmaceuticals and another letter to the CMS from GE Healthcare. See JA 29–32, 38–41. However, because neither Mallinckrodt Pharmaceuticals nor GE Healthcare indicated in their letters whether they were members of the Council, the Court did not take these letters into consideration when determining whether the Council had established that one of its members had standing to sue in its own right.

insufficient to confer standing upon the Council because neither declaration establishes that either member has been harmed or will be harmed by the Final Rule.

With respect to the declaration submitted by Dan Brague, the Chief Executive Office of Curium, this declaration fails to show that Curium will suffer economic injury, as the Council claims. Brague claims that Curium, if it were to enter into a Medicaid Drug Rebate Program Agreement, "would have to expend significant resources to implement new programs and install new systems to administer the [Medicaid Drug Rebate] Program." Pl.'s Opp'n, Ex. A (Curium Decl.) ¶ 10. However, Brague concedes that "Curium . . . does not currently participate in the Medicaid Drug Rebate Program and has not entered into a Medicaid Drug Rebate Program Agreement," id., Ex. A (Curium Decl.) ¶ 8, and he does not assert that Curium intends to participate in the Medicaid Drug Rebate Program in the future, see generally id., Ex. A (Curium Decl.). And, because participation in the Medicaid Drug Rebate Program is not mandatory for drug manufacturers, but rather is only required in order to receive state Medicaid payments for its covered outpatient drugs, see Thompson, 251 F.3d at 221; see also 42 U.S.C. § 1396r-8(a), (b), Brague's declaration fails to establish that Curium will even likely be required to comply with the requirements of the Medicaid Drug Rebate Program, cf. Humane Soc. v. Babbitt, 46 F.3d 93, 97 (D.C. Cir. 1995) (finding that the plaintiff could not establish that it had standing because its supporting declaration lacked allegations demonstrating that the injury was imminent). Thus, Curium's alleged harm asserted in Brague's declaration is not imminent, but purely speculative, and therefore, is not sufficient to establish that Curium has standing to sue in its own right.

The declaration submitted by Roger Estafanos, the Head of Pricing and Market Access at Advance Accelerator Applications, also fails to establish that Advance Accelerator Applications

has standing to sue in its right. Estafanos represents that Advance Accelerator Applications "currently participates in the Medicaid Drug Rebate Program and has entered into a Medicaid Drug Rebate Program Agreement," Pl.'s Opp'n, Ex. B (AAA Decl.) ¶ 8, and that because the CMS "provides little to no guidance on how radiopharmaceutical manufacturers are to comply with the[] [Medicaid Drug Rebate Program's] reporting requirements," id., Ex. B (AAA Decl.) ¶ 10., "manufacturers [must] make good-faith, reasonable assumptions about how to satisfy the reporting requirements," id., Ex. B (AAA Decl.) ¶ 15 (claiming that "the general lack of specific reporting standards relating to radiopharmaceuticals, and [the] CMS's refusal to clarify how radiopharmaceutical manufacturers are to comply with these requirements necessitates that manufacturers make good-faith, reasonable assumptions about how to satisfy the reporting requirements"). However, this general statement that Advance Accelerator Applications must make assumptions about how to satisfy its reporting obligations is insufficient to establish that Advance Accelerator Applications has suffered a concrete harm, without any allegation establishing either that its assumptions have resulted in its noncompliance with the regulations or that there is a substantial risk that it will be found noncompliant with the regulations. Cf. State Nat. Bank v. Lew, 795 F.3d 48, 53 (D.C. Cir. 2015) (finding that the plaintiff had standing to challenge regulations because it "indeed alleged [in its affidavit] that it must now monitor its remittances to stay within the safe harbor[] and [that] the monitoring program causes it to incur costs"). In addition, contrary to the Council's assertions that "[the participating] members [will] incur administrative costs associated with ongoing reporting of product data and processing rebate claims, as well as liability for the rebate amounts themselves," Pl.'s Opp'n at 5, and that the Final Rule "exposes [its] members to injuries that flow from the inability to report product and pricing data—the risk of civil penalties and enforcement, and the risks to product coverage,"

id. at 6, Estafanos does not claim that Advance Accelerator Applications has incurred or will incur any additional costs, see generally id., Ex. B (AAA Decl.). Thus, because Estafanos's declaration does not allege sufficient facts to support that Advance Accelerator Applications has suffered or will suffer an injury as a result of participating in the Medicaid Drug Rebate Program, the Court finds that Advance Accelerator Applications has failed to establish its standing to sue in its own right as well.

Therefore, because neither declaration submitted by the Council establishes that at least one of its members has standing, the Court concludes that the Council has failed to carry its burden of showing that it has standing to sue as an association on behalf of its members. Thus, the Court finds that summary judgment in favor of the defendants is required.

IV. CONCLUSION

For the foregoing reasons, the Court concludes that the Council has failed to establish that one of its members has standing to sue in its own right. Accordingly, the Court will grant the defendants' summary judgment motion and deny the plaintiff's motion for summary judgment.

SO ORDERED this 13th day of November, 2019.[5]

REGGIE B. WALTON
United States District Judge

[5] The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.