UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STIMLABS, LLC, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil No. 22-cv-01988 (APM)**
XAVIER BECERRA, *et al.*, *Secretary of Health and Human Services*,	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

Plaintiff StimLabs, LLC ("StimLabs") is a biotechnology company that develops and sells products for wound care and amniotic fluid allografts. At issue in this case are two of its products—Ascent and Corplex P—which are categorized as human cell, tissue, and cellular and tissue-based products, or HCT/Ps. StimLabs' Ascent and Corplex P "are used to cushion and protect open wound environments and to cushion, protect, and supplement fluid environments such as synovial joints and tendons, and are distinct from drugs and biologicals, which require metabolic activity to achieve a therapeutic effect." Two companies that use those products join as plaintiffs: Plaintiff Anesthesia and Pain Consultants, PC ("APC") is a physician-owned corporation that provides medical care, and Plaintiff Wound Institute of America, Inc. ("Wound Institute") is a medical practice focused on surgical and non-surgical wound care.

Plaintiffs brought this action to challenge purported policies barring reimbursement for the use of Ascent and Corplex P under the Medicare program. Plaintiffs allege that the Secretary of Health and Human Services (the "Secretary") and the Administrator of the Center for Medicare

and Medicaid Services ("CMS") (together, "Defendants") unlawfully bypassed the notice-and-comment-rulemaking requirement for policies that change a substantive legal standard governing Medicare coverage and payment, and that Defendants applied those policy changes retroactively, contrary to law. Additionally, Plaintiffs assert that Defendants' decision to stop covering Ascent and Corplex P is arbitrary and capricious under the Administrative Procedure Act ("APA").

Before the court are Plaintiffs' motion for a preliminary injunction and Defendants' motion to dismiss. The court concludes that Plaintiffs failed to exhaust their administrative remedies before filing suit. Therefore, the court lacks subject matter jurisdiction over this action. Accordingly, Defendants' motion to dismiss is granted and Plaintiffs' motion for a preliminary injunction is denied.

II. BACKGROUND

A. The Medicare Program and Coverage for Use of HCT/Ps

The Medicare program is a nationwide health insurance program for the aged, blind, and disabled. Part B of the program covers hospital-outpatient services, physician services, and other services not covered by Part A. Among the covered services under Part B are "drugs and biologicals which are not usually self-administered by the patient." 42 U.S.C. § 1395x(s)(2)(A). The Medicare program will not cover any service that is "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a)(1)(A). The Secretary's regulations limit Medicare coverage only to drug products that have been approved by the U.S. Food and Drug Administration ("FDA"). 42 C.F.R. § 410.29 (2021). The regulations purportedly do "not require prior FDA approval for HCT/Ps," like Ascent and Corplex P, "that are not regulated as drugs." Compl. for Inj. and Decl. Relief, Mandamus, and Relief Under the All Writs Act, ECF No. 1 [hereinafter Compl.] ¶ 1.

Further, the Secretary has not published a final rule addressing Medicare coverage for HCT/Ps. *Id.* ¶ 64

In November 2017, the FDA published guidance setting out the "FDA's position for manufacturers" on what qualified as "minimal manipulation and homologous use"—a requirement for products to be regulated as HCT/Ps. *Id.* ¶ 49. The guidance provided a period of time during which the FDA "intended to exercise enforcement discretion while manufacturers determined whether their products met the HCT/P criteria, as freshly interpreted by the FDA," relieving manufacturers "of all premarket review and approval requirements" during this period. *Id.* The enforcement discretion was set to expire on May 31, 2021. *Id.* ¶ 50.

On December 6, 2019, in the midst of the enforcement discretion period, the FDA issued a Guidance and Public Safety Notification ("FDA Notification") that declared a specific subset of HCT/Ps as "experimental exosome biological products." *Id.* ¶ 2. The FDA Notification did not apply to all HCT/Ps and, in fact, was "entirely silent as to HCT/Ps derived from amniotic cells, placental cells, or tissues," like StimLab's Ascent and Corplex P, which are not exosomes. *Id.* ¶ 59.

Nevertheless, in July 2021, after the FDA's enforcement discretion period ended, Medicare Administrative Contractors ("MACs") began denying reimbursement claims for Ascent and Corplex P based on the FDA Notification. *Id.* ¶¶ 2, 52–53. According to Plaintiffs, this change marked a sharp departure from Medicare's past coverage of Ascent and Corplex P. Before May 31, 2021, MACs "routinely covered and paid Medicare Part B claims for products composed of amniotic tissue, including Ascent and Corplex P, as reasonable and necessary." *Id.* ¶ 52. However, in July 2021, "MACs began retroactively reopening claims" for Ascent and Corplex, without providing any notice to providers and suppliers of the change in Medicare coverage for

HCT/Ps, and without engaging in notice-and-comment rulemaking. *Id.* ¶ 53. In short, MACs began refusing to reimburse for the use of Ascent and Corplex P in treatment, despite the fact that they are not "experimental exosome biological products" and have not been categorized as such by the FDA. *Id.* ¶ 3. One MAC denied claims for services using Corplex P on the grounds that "Corplex P was not approved by the FDA," and another MAC denied claims for Ascent because "Ascent was experimental/investigational." *Id.* ¶¶ 54, 56.

After a MAC began denying claims for Ascent, StimLabs took the matter up with CMS. It "contacted the Director, Coverage and Analysis Group at CMS to discuss the actions [and] . . . [o]ver the course of several months, StimLabs engaged in multiple email exchanges and several telephone calls to discuss the use of an unpublished policy memorandum, the absence of any notice that the coverage criteria had changed, and the use of a rationale that did not reflect the legal status of Ascent as an HCT/P." *Id.* ¶ 55.

B. The Technical Direction Letters

In February 2022, CMS issued two Technical Direction Letters ("TDLs") regarding HCT/Ps. The TDLs (1) "declared that certain manipulated amniotic and/or placental tissue biologics for injections were experimental exosome biologic products and (2) directed the MACs to re-open and adjust any paid claims for dates of service December 6, 2019, and later for those HCT/Ps identified in the TDLs." *Id.* ¶ 61 (internal quotation marks omitted). The "TDLs also directed the MACs to apply automatic claims denials, rather than the claim-by-claim determinations that otherwise apply in the absence of [a national coverage determination] or [a local coverage determination], specifically identifying . . . Ascent and Corplex P for such automatic denial." *Id.* In addition to failing to adopt the TDLs through notice-and-comment, according to Plaintiffs, CMS further sought to obscure its actions. "CMS expressly directed the

MACs not to reference CMS's TDLs in any ad hoc provider education regarding the Policies." *Id.*

On February 23, 2022, "MACs released policies on their websites stating that Medicare claims for manipulated, reconstituted, or injectable amniotic, or placental products would no longer be covered under Medicare." *Id.* ¶ 58. The policies further stated that "claims with dates of service on or after December 9, 2019, would be reopened and retroactively denied." *Id.* In early March 2022, "StimLabs again contacted CMS as well as the FDA to seek a resolution of the matter." *Id.* ¶ 60. StimLabs met with the director of CMS's Coverage and Analysis Group and had a conference call with an FDA Associate Director for Product Management, but the "contacts proved fruitless." *Id.*

The TDLs were short-lived. On March 25, 2022, CMS issued a third TDL that withdrew the first two. *Id.* ¶ 62. CMS instructed MACs to "suspend automatic denials of claims for amniotic and placental tissue product injections," to "institute claim-by-claim review to determine whether a claim meets the reasonable and necessary criteria," and "to reopen any claims that had been processed under the automatic denials." *Id.* Despite the withdrawal of the TDLs, Plaintiffs allege that MACs "reinstituted their denials of Medicare claims for HCT/P products including Ascent and Corplex P . . . on the same rationale articulated in the TDLs, asserting that the claims can be denied because neither Ascent nor Corplex P has received premarket approval from the FDA, even though FDA approval is not required for HCT/P products." *Id.* ¶ 63. In other words, Plaintiffs claim that, despite the February 2022 TDLs being rescinded, MACs continued to deny coverage for Ascent and Corplex P under their reasoning.

This alleged new unwritten coverage policy threatens the viability of Plaintiffs' businesses. StimLabs says "that a loss of Medicare coverage for Corplex P alone will result in a loss of

approximately 20% of its current revenue that cannot be compensated through damages." *Id.* ¶ 65. Plaintiff APC has submitted Medicare reimbursement claims for its use of Ascent, and it has received overpayment notices totaling approximately $200,000. *Id.* ¶ 67. If forced to repay the overpayment demand, APC would have to close its practice. *Id.* ¶¶ 67, 85. The Complaint does not allege that Plaintiff Wound Institute has received an overpayment notice but does state that it has "lost revenue" and "faces significant damage to its professional reputation and good will." *Id.* ¶ 103.

C. Procedural History

Plaintiffs filed this action and moved for preliminary injunctive and declaratory relief on July 8, 2022. *See* Compl.; Pls.' Mot. for Inj. and Decl. Relief, ECF No. 6 [hereinafter Pls.' Mot.], Pls.' Mem. of P. & A. in Supp. of Pls.' Mot., ECF No. 6-1 [hereinafter Pls.' Inj. Mem.]. Plaintiffs allege that CMS's unwritten blanket policy of denying coverage for the use of Ascent and Corplex P (1) violates 42 U.S.C. § 1395hh, which "expressly requires that a change in a substantive legal standard governing the scope of Medicare benefits or payments be subject to notice and comment rulemaking," (2) is arbitrary and capricious in violation of Section 706 of APA, and (3) runs afoul of both 42 U.S.C. § 1395hh(e) and 42 C.F.R. § 405.980 due to the retroactive application of the new policy without a finding of good cause. Pls.' Inj. Mem. at 2. Plaintiffs ask the court to declare the Secretary's actions invalid and unlawful, and to enjoin the Secretary from implementing them. *Id.* at 45.

Defendants filed a motion to dismiss on August 15, 2022. Defs.' Mem. of P. & A. in Supp. of their Mot. and in Opp'n to Pls.' Mot., ECF No. 17 [hereinafter Defs.' Mot.]. As grounds for dismissal, Defendants argue both that the court lacks subject matter jurisdiction and that Plaintiffs

have failed to state a claim. *See id.* Because the court dismisses this action on jurisdictional grounds, it does not address the sufficiency of Plaintiffs' pleading.

III. DISCUSSION

A. Federal Question Jurisdiction: 28 U.S.C. § 1331

The parties' primary jurisdictional dispute centers on whether the court lacks general federal question jurisdiction to hear this action. It is "well established that section 405(h) of the Social Security Act (as incorporated into the Medicare Act through 42 U.S.C. § 1395ii) expressly limits the availability of general federal question jurisdiction in the Medicare context." *California Clinical Lab'y Ass'n v. Sec'y of Health & Hum. Servs.*, 104 F. Supp. 3d 66, 80 (D.D.C. 2015); 42 U.S.C. § 405(h) ("No action . . . shall be brought under section 1331 . . . of Title 28 to recover on any claim arising under" the Medicare Act). Section 405(h) "channels most, if not all, Medicare claims through [the agency] review system." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8 (2000). Generally speaking, only after exhausting agency review procedures can claimants "seek judicial review [in federal court] pursuant to the Medicare Act." *Council for Urological Ints. v. Sebelius*, 668 F.3d 704, 706 (D.C. Cir. 2011); *see* 42 U.S.C. § 1395ff(b)(1)(A) (providing for "judicial review of the Secretary's final decision" following an administrative hearing).

"This nearly absolute channeling requirement assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by individual courts applying 'ripeness' and 'exhaustion' exceptions case by case." *Ill. Council*, 529 U.S. at 2. The Supreme Court has recognized that the "assurance comes at the price of occasional individual, delay-related hardship, but paying such a price in the context of a massive, complex health and safety program such as Medicare was justified in the judgment of Congress."

Id. Thus, section 405(h) "is intended to postpone judicial review, not totally preclude it." *Council for Urological Ints.*, 668 F.3d at 708.

In *Illinois Council*, the Court recognized an exception to the channeling requirement. The Court said that "§ 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean *no review at all*." *Ill. Council*, 529 U.S. at 19 (emphasis added). In other words, for claims arising under the Medicare Act, if the channeling requirement leads to a "*complete* preclusion of judicial review," a party need not present and exhaust its claims before coming to federal court. *Id.* at 23. The *Illinois Council* exception is a narrow one, however. It is "not intended to allow section 1331 federal question jurisdiction in every case where section 405(h) would prevent a particular individual or entity from seeking judicial review." *Council for Urological Ints.*, 668 F.3d at 711.

Taken together, these principles require a "three-step analysis" to assess "whether a court has subject matter jurisdiction to hear a claim related to Medicare." *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 976 (9th Cir. 2020). First, the court must determine whether the claim "arises under" the Medicare Act. *Id.* If it does, the court next "must decide whether the plaintiff has satisfied the channeling requirements by properly presenting the claim and exhausting the appropriate administrative channel." *Id.* Finally, if plaintiff has not satisfied the channeling requirement, the court must inquire whether the "no review at all" exception applies. *Id.* "If it [does], the plaintiff may proceed in court under 28 U.S.C. § 1331 or some other jurisdictional predicate. If not, the plaintiff's claim cannot proceed and must be dismissed for lack of subject matter jurisdiction." *Id.*

Here, the parties agree that Plaintiffs' claims "arise under" the Medicare Act and that Plaintiffs have not satisfied the channeling requirement. Defs.' Mot. at 10–17; Pls.' Mem. of L.

in Opp. to Defs.' Mot., ECF No. 23 [hereinafter Pls.' Reply], at 7–12. Their dispute is over whether Plaintiffs meet the *Illinois Council* "no review at all" exception. Defs.' Mot. at 16–17; Pls.' Reply at 7–12.

Plaintiffs effectively concede that APC and Wound Institute cannot meet the exception. Both are Medicare enrolled providers who are eligible to appeal the denial of coverage and overpayment notices for the use of StimLabs' products. In fact, APC has filed an appeal and it remains pending in the administrative process. Pls.' Mot., Pls.' Ex. 3, ECF No. 6-4 [hereinafter Dooley Decl.], ¶¶ 6, 8. APC and Wound Institute therefore cannot establish that they are completely precluded from administrative review.

Plaintiffs' jurisdictional hopes thus rest on StimLabs. They contend that "StimLabs falls squarely within the exception to the 'channeling' requirement'" because "StimLabs is not a provider and as such is an affected party that has no avenue for administrative review." Pls.' Reply at 11. Plaintiffs continue, "StimLabs is not required to, nor is it acting as the assignee of a Medicare beneficiary or supplier" and "the resulting decision would only apply to that individual claim and would not result in a global resolution." *Id.* Plaintiffs emphasize that they are challenging "the validity of the Policies and actions, not any present or past individual claim for Medicare reimbursement," and that "the relief Plaintiffs seek is entirely procedural because their goal is to ensure that any consideration of their claims will be conducted only under valid regulations and that any reopenings comply with existing regulations." Pls. Mem. at 19; Pls. Reply at 14.

But the fact that, as a non-provider, StimLabs is unable to assert a claim directly, is challenging a policy and not an individual claim, and is seeking only procedural relief does not excuse it from the channeling requirement. To meet the *Illinois Council* exception, StimLabs still must show that there is not an "adequate proxy" that could raise claims on its behalf. *Council for*

Urological Ints., 668 F.3d at 712. It has not done so. Providers of StimLabs' products, such as co-Plaintiffs APC and Wound Institute, are more than adequate proxies. Such providers have an obvious incentive to present claims and exhaust administrative remedies: if they do not challenge the denial of coverage and overpayment notices, they will be required to repay large sums to CMS and will not be reimbursed for future use of the products. APC alone claims to have received over $200,000 in overpayment notices. Dooley Decl. ¶ 14. Moreover, these providers will not have to pursue administrative remedies on their own. StimLabs will offer a helping hand. According to StimLabs, it employs a Director of Reimbursement Support who is "responsible for filing appeals on StimLabs' products including Ascent and Corplex P." Pls.' Mot., Pls.' Ex. 10, ECF No. 6-11, ¶ 3. Thus, this is not a case where, because "the only entities able to invoke Medicare Act review are highly unlikely to do so, their unwillingness to pursue a Medicare Act claim poses a serious 'practical roadblock' to judicial review." *Council for Urological Ints.*, 668 F.3d at 712. The providers who use StimLabs' products are an "adequate proxy" to present claims. *See RICU LLC v. U.S. Dep't of Health & Hum. Servs.*, 22 F.4th 1031, 1038–39 (D.C. Cir. 2022) (holding that the "client hospitals" of a telehealth medicine company were an adequate proxy to seek reimbursement for incurred physicians' costs).

Plaintiffs' arguments to the contrary are unpersuasive. Citing *Baxter Healthcare Corp. v. Weeks*, Plaintiffs primarily contend that "StimLabs is not required to recruit parties to bring an administrative claim on its behalf." Pls.' Reply at 10 (citing *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 116 (D.D.C. 2018) ("[*American Chiropractic Ass'n v. Leavitt*, 431 F.3d 812 (D.C. Cir. 2005)] does not require Baxter to recruit a physician or hospital to act as its proxy in an administrative process."). Defendants respond that the language in *Baxter* is a "misstatement of the law[,] . . . misapplies D.C. Circuit precedent[,] and stands out as an aberration." Defs.' Reply

Mem. in Supp. of Mot. to Dismiss, ECF No. 24 [hereinafter Defs.' Reply], at 6. The court agrees that *Baxter* does not withstand scrutiny.

The D.C. Circuit's recent decision in *RICU* illustrates why. In that case, the plaintiff was an inpatient telehealth company that specialized in remote critical care services and contracted with U.S.-trained intensive-care physicians who lived and worked abroad. 22 F.4th 1031, 1033 (D.C. Cir. 2022). "[C]lient hospitals" paid the plaintiff for the services provided by these physicians. *Id.* at 1033. CMS ruled that "Medicare could not reimburse any telehealth services furnished by medical providers outside the United States." *Id.* at 1034. Not itself a provider, the plaintiff attempted to establish jurisdiction to sue under the Medicare Act by invoking the *Illinois Council* exception, but the D.C. Circuit rejected the effort. *Id.* at 1038–39. It held that the "client hospitals are adequate proxies to channel [the plaintiff's] general claim that its services are eligible for Medicare reimbursement through a concrete claim for payment." *Id.* at 1039. In reaching this conclusion, the court considered whether the client hospitals' interests aligned with the plaintiff's, ultimately concluding that they did because "these [hospitals] want the Department [of Health and Human Services] to allow reimbursement so they can more readily maintain or even expand their contracts with [the plaintiff]." *Id.*

The same is true here. Plaintiff StimLabs' interests directly align with the interests of providers such as APC and Wound Institute. A favorable coverage determination will relieve providers of overpayment obligations, thus promoting their financial health, and will secure future use of the products. Furthermore, even if the court were to follow *Baxter*'s reasoning, StimLabs has already "recruited" a provider that can "seek administrative review of its claims." *Baxter*, 643 F. Supp. 2d at 116 (cleaned up). APC has filed an administrative appeal, presumably with StimLabs' help, Pls.' Ex. 3 ¶¶ 6–10, and the court is given no reason to think Wound Institute

cannot do the same. Thus, the court need not speculate whether StimLabs could "recruit" a proxy—it already has done so.

Plaintiffs' reliance on the out-of-Circuit decision in *Akebia Therapeutics v. Becerra* also is misplaced. Pls.' Reply 9–11; 548 F. Supp. 3d 274 (D. Mass 2021). There, the plaintiff was a drug manufacturer who sought judicial review of a CMS decision eliminating coverage for its drug. *Akebia*, 548 F. Supp. 3d at 276. The court determined the *Illinois Council* exception applied because the plaintiff was "not an association whose members could challenge CMS's decision administratively," was part of a "category of entities" (drug manufacturers) that are "wholly excluded from the Part D administrative review process," and there was nothing to suggest the plaintiff "could act as a Part D participant's assignee or appointed representative." *Id.* at 286–87. The court further reasoned that the exception applied because "an individual Part D participant can challenge only an individual coverage determination . . . not a generally-applicable decision by the Government." *Id.* at 297. But *Akebia* does not move the dial because it rejects the very D.C. Circuit precedent to which this court is bound. The court in *Akebia* described *Council for Urological Interests* as an "outlier and generally at odds with the trend in the case law that the applicability of the 'no review' exception depends on whether there is something the plaintiff can do to facilitate administrative review." *Id.* at 286 n.14 (observing that "under the logic of *Council for Urological Interests*, the fact that Akebia cannot bring about administrative review could be considered unimportant because Part D participants are incentivized to do so (and have)"). This court, of course, is not free to dismiss *Council for Urological Interests* as an "outlier."

In short, because providers of StimLabs' products are an adequate proxy to channel StimLabs' general claim that its products are eligible for Medicare coverage, the *Illinois Council* exception does not apply, and thus the court lacks federal question jurisdiction over this action.

B. Medicare Act Jurisdiction: 42 U.S.C. § 405(g)

Alternatively, Plaintiffs contend that they have met the jurisdictional requirements of 42 U.S.C. § 405(g). Pls.' Reply at 12–16. According to Plaintiffs, they both presented their claims to the agency and qualify for waiver of the exhaustion requirement because the challenges they have raised are "collateral to the claims for benefits." *Id.* at 12–13 (quoting *Bowen v. City of New York*, 476 U.S. 467, 483 (1986)). Specifically, Plaintiffs assert that "the 'exhaustion' requirement should be waived because the Plaintiffs' arguments are 'entirely collateral' to any claims that could be raised in an administrative proceeding because those proceedings are limited to reviews of individual claims and cannot make a determination that the Secretary failed to comply with Section 1395hh(a)(2) or the limits on reopenings of Medicare claims." *Id.* at 14.

Section 405(g) creates two prerequisites for judicial review: (1) "a plaintiff's claim must have been presented to the Secretary," and (2) "a plaintiff must fully exhaust the administrative remedies prescribed by the Secretary." *RICU*, 22 F.4th at 1036 (quoting *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)) (cleaned up). The presentment requirement is a "nonwaivable element" of jurisdiction. *Mathews*, 424 U.S. at 328; *RICU*, 22 F.4th at 1036 ("Section[] 405(g) . . . effectively preclude[s] the exercise of district court jurisdiction in the absence of presentment of a concrete dispute, regardless of the nature of the claim at issue."). Exhaustion is waivable, and "[w]aiver is warranted if the claim is (1) collateral to a substantive claim of entitlement (collaterality); (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability); and (3) one whose resolution would not serve the purposes of exhaustion (futility)." *Sensory Neurostimulation*, 977 F.3d at 981 (internal quotation marks omitted); *see also Bowen*, 476 U.S. at 483 (stating that courts can waive § 405(g)'s exhaustion requirement where the claim is "entirely

collateral to [a] substantive claim of entitlement" and "the claim rest[s] 'on the proposition that full relief cannot be obtained at a postdeprivation hearing'") (quoting *Mathews*, 424 U.S. at 331).

At the outset, the court concludes that StimLabs has not met the presentment requirement. Plaintiffs insist that StimLabs presented a claim because its representatives "repeatedly contacted multiple agencies, including a MAC, CMS, and the FDA in order to explain" its position on coverage. Pls.' Reply at 14 (citing Pls.' Mot., Pls.' Ex. 2, ECF No. 6-3, ¶ 9 (StimLabs provided coverage criteria to a MAC); *id.* ¶¶ 13–14 (StimLabs expressed "concerns" to CMS through emails and phone calls about a MAC's auditing and denial of Ascent claims); *id.* ¶¶ 20–22 (StimLabs advised a MAC that clinical trials were not required for its products); Pls.' Mot., Pls.' Ex. 6, ECF No. 6-7, ¶¶ 2–3 (describing two telephone communications between counsel for StimLabs and representatives of CMS and FDA)). But that is not correct. "Presentment instead demand[s] that the Department have 'an opportunity to rule on a concrete claim for reimbursement.'" *RICU*, 22 F.4th at 1036 (quoting *Heckler v. Ringer*, 466 U.S. 602, 622 (1984)). Merely raising concerns generally about coverage decisions outside of the administrative process for a specific claim, as StimLabs did here, is not sufficient. *See id.* at 1037 (holding that mere request for guidance on how to apply an interim rule did not satisfy the presentment requirement).

Unlike StimLabs, APC is challenging through the Medicare administrative appeals process specific adverse decisions with respect to its use of Ascent. Dooley Decl. ¶¶ 6–8 (stating that APC has "appealed through the Redetermination phase of the Medicare appeals process" and has further appealed to "the qualified independent contractor responsible for the appeal of [the MAC's] decision"). Still, Plaintiffs have not shown that APC has met the presentment requirement. "[A]ll aspects" of a claim must be channeled. *Heckler*, 466 U.S. at 614. That means a claimant cannot bring a challenge in federal court that it has not raised before the agency. *See Am. Hosp.*

Ass'n v. Azar, 895 F.3d 822, 826 (D.C. Cir. 2018) (holding that the plaintiffs had not satisfied the presentment requirement where none of them "had challenged the new reimbursement regulation in the context of a specific administrative claim for payment"). Plaintiffs have put neither APC's appeal nor the MAC's determination letter before the court, so the court cannot say for sure on what grounds APC contested the overpayment notice. APC's declarant has described the basis for the MAC's adverse ruling, but that summary makes it seem that APC's claim was denied because the MAC deemed the use of Ascent not to be "reasonable and necessary." Dooley Decl. ¶ 7 (noting that the MAC's decision rested in part on Ascent being "experimental/investigational"). Thus, when Plaintiffs filed this suit, none of them appear to have challenged CMS's purported unwritten policy on the grounds advanced here "in the context of a specific administrative claim for payment." *Am. Hosp. Ass'n*, 895 F.3d at 826. Accordingly, the court finds that Plaintiffs have failed to meet the "presentment" requirement under § 405(g).

Waiver of the exhaustion requirement also would not be appropriate. Plaintiffs' challenge here is not "collateral to the claims for benefits." *Bowen*, 476 U.S. at 483. It is directly related to the reasons for the denials themselves. According to Plaintiffs, Medicare's policy of covering only approved FDA drug products does not apply to HCT/Ps because they "are not regulated as drugs" and thus do "not require prior FDA approval." Compl. ¶¶ 20, 42 ("These HCT/Ps are not regulated as drugs, biologics, or medical devices and no premarket submissions are required for FDA review or approval."). Yet, they allege, since the rescission of the TDLs, MACs have continued to reopen and wrongly deny coverage for their products, often "on the same rationale articulated in the TDLs, asserting that the claims can be denied because neither Ascent nor Corplex P has received premarket approval from the FDA, *even though FDA approval is not required for HCT/P products*." *Id.* ¶ 63 (emphasis added). Thus, Plaintiffs' complaint, at bottom, seems to be that

CMS's "unwritten policy" of denying coverage for Ascent and Corplex P is based on a basic misunderstanding of their products, *see id.* ¶ 59 (asserting that StimLabs' products are not exosome products that were the subject of the FDA's December 2019 Public Safety Notification), and a mistaken application of its own regulations, which *do not* require FDA approval for HCT/Ps, *id.* ¶ 20. Such challenges are not "collateral" to the benefits denials. *See Bowen*, 476 U.S. at 483. They are central to the benefits denials themselves.

Additionally, waiver of the exhaustion requirement is unwarranted because no Plaintiff has plausibly established that it would be irreparably harmed if it were required to channel its claims. Plaintiffs maintain that, "[o]n information and belief, StimLabs estimates that a loss of Medicare coverage for Corplex P alone will result in a loss of approximately 20% of its current revenue that cannot be compensated through damages." Compl. ¶ 65; Pls. Mot., Ex. 4, ECF No. 6-5 [hereinafter Steele Decl.] ¶ 13. But it is settled in this Circuit that "[r]ecoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant's business." *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985).[1] StimLabs' claimed revenue loss does not meet that stringent standard. APC also contends that it has received approximately $200,000 in overpayment demands, "which if fully recouped *could result* in the shuttering of [the] practice." Dooley Decl. ¶ 14 (emphasis added). That recoupment "could result" in business harm is too thin a reed on which to plausibly establish irreparable harm.

[1] StimLabs also asserts that the downstream effects of CMS's actions will cause "approximately $23 Million in losses associated with the discontinuation of Corplex P products this year alone," which along with potential repayments to customers, threatens StimLabs' "ability to continue as a going concern." Steele Decl. ¶¶ 15–16. But this magnitude of losses appears speculative. StimLabs does not, for example, explain what percentage of its providers depend on Medicare for reimbursement, such that they are likely to discontinue using its products. Moreover, to the extent that CMS's denial of coverage has resulted in providers demanding refunds, that would appear to be a consequence of StimLabs' apparent business decision to indemnify its customers in the event of coverage denials, not any agency action.

C. Mandamus Act Jurisdiction: 28 U.S.C. § 1361

Plaintiffs also invoke the court's jurisdiction pursuant to the Mandamus Act, 28 U.S.C. § 1361. The D.C. Circuit has held that mandamus jurisdiction is not precluded by § 405(h). *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813 (D.C. Cir. 2001). Such relief is available in the Medicare Act context, however, only "to review otherwise unreviewable procedural issues" that are "unrelated to the merits." *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 765–66 (5th Cir. 2011). As discussed already, Plaintiffs' procedural claims here are *not* unrelated to the merits; on the contrary, they rest on Plaintiffs' merits contention that CMS in fact has changed its coverage policy. For that reason alone, the exercise of mandamus jurisdiction is not appropriate.

Additionally, mandamus relief is available only if: "(1) the plaintiff has a clear right to relief; (2) the defendant has a clear duty to act; and (3) there is no other adequate remedy available to the plaintiff." *Council of & for the Blind of Del. Cnty. Valley, Inc. v. Regan*, 709 F.2d 1521, 1533 (D.C. Cir. 1983). Even if all jurisdictional requirements are met, "a court may grant relief only when it finds compelling equitable grounds." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (internal quotation marks omitted). "The party seeking mandamus has the burden of showing that its right to issuance of the writ is clear and indisputable." *Id.* (internal quotation marks omitted).

Here, Plaintiffs have not met their burden. For starters, Plaintiffs have not shown that the administrative appeals process is not an adequate remedy. This by itself bars mandamus jurisdiction. *See Monmouth*, 257 F.3d at 810 ("[W]e must first examine all other possible avenues of relief to ensure that the hospitals have fully exhausted those which were available."); *id.* at 813 (stating that mandamus is available only when the claimant has exhausted administrative remedies).

Moreover, mandamus relief is unavailable because there is no clear, "ministerial" duty to act. Plaintiffs argue that "the Secretary has a clear duty to inform the MACs that they may no longer follow the policy in question and to instruct them to stop engaging the reopening of claims on grounds that are prohibited by statute." Pls.' Reply at 19. Similar mandamus requests have been rejected by district courts in this Circuit. For example, in *California Clinical*, the plaintiff sought "[a]n order mandating the Secretary and her agents, including MACs, to comply with all applicable provisions of the Constitution and the Medicare Act," similarly over a dispute regarding the Secretary's alleged failure to engage in notice-and-comment rulemaking. 104 F. Supp. 3d at 83–84. Then-Judge Ketanji Brown Jackson rejected mandamus jurisdiction, because the plaintiff had "neither demonstrated that it has any clear right to an order requiring the Secretary to comply with these procedural mandates, nor has it shown that the Secretary has any clear, nondiscretionary duty to act under the provisions at issue." *Id.* at 84. The same is true here.

Simply put, Plaintiffs have not plausibly established that this is the type of "extraordinary case" in which the "drastic remedy" of mandamus would be proper. *Id.* at 83.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss, ECF No. 17, is granted, and Plaintiffs' Motion for Preliminary Injunction, ECF No. 6, is denied. A separate, final order accompanies this Memorandum Opinion.

Dated: October 21, 2022

Amit P. Mehta
United States District Judge