Selected docket entries for case 23−5020

Generated: 09/27/2023 15:07:11

Filed	Document Description	Page	Docket Text
05/03/2023	Appellant/Petitioner Brief Filed	2	APPELLANT BRIEF [1997771] filed by Row 1 Inc. [Service Date: 05/03/2023] Length of Brief: 7,951 words, excluding the parts of the brief exempted by Circuit Rule 32(e)(1).. [23−5020] (Pandya, Brian)
06/07/2023	Appellee/Respondent Brief Filed	62	APPELLEE BRIEF [2002657] filed by Xavier Becerra, Chiquita Brooks−LaSure, Centers for Medicare and Medicaid Services, CGS Administrators, LLC, First Coast Service Options, Inc., HHS, National Government Services Inc., Noridian Healthcare Solutions, LLC, Novitas Solutions, Inc., Palmetto GBA, LLC and Wisconsin Physicians Service Insurance Corporation [Service Date: 06/07/2023] Length of Brief: 12,370 words. [23−5020] (Lopez, Caroline)
06/28/2023	Appellant/Petitioner Reply Brief Filed	139	APPELLANT REPLY BRIEF [2005452] filed by Row 1 Inc. [Service Date: 06/28/2023] Length of Brief: Brief contains 6,002 words, excluding the parts of the brief exempted by Circuit Rule 32(e)(1).. [23−5020] (Pandya, Brian)

ORAL ARGUMENT NOT YET SCHEDULED

No. 23-5020

UNITED STATES COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA CIRCUIT

ROW 1 INC. D/B/A REGENATIVE LABS,

Appellant

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, SOLELY IN HIS OFFICIAL CAPACITY; ET AL.,

Appellees

On Appeal from the Order and Opinion of the United States District Court for the District of Columbia, Case No. 22-cv-0718, dated January 12, 2023

Brief of Appellant
Row 1 Inc. d/b/a Regenative Labs

BRIAN H. PANDYA
FREDERICK R. BALL
ROBERT M. PALUMBOS
DUANE MORRIS LLP
901 New York Ave. NW, Suite 700-East
Washington, DC 20001
(202) 776-7800

Counsel for Appellant
Row 1 Inc. d/b/a Regenative Labs

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

1. Parties and Amici

The following parties, intervenors, and amici curiae appeared before the district court:

- Plaintiff in this matter is Row 1 Inc. d/b/a/ Regenative Labs ("Regenative").
- Defendants are the following parties:
  - Xavier Becerra ("Becerra"), solely in his official capacity as Secretary of the United States Department of Health and Human Services;
  - The United States Department of Health and Human Services ("HHS");
  - Chiquita Brooks-Lasure ("LaSure"), solely in her official capacity as Administrator of the Centers for Medicare and Medicaid Services;
  - The Centers for Medicare and Medicaid Services ("CMS");
  - Palmetto GBA, LLC ("Palmetto");
  - Noridian Healthcare Solutions, LLC ("Noridian");
  - Wisconsin Physicians Service Insurance Corporation ("WPS");
  - Novitas Solutions, Inc. ("Novitas");

- National Government Services, Inc. ("NGS");
- CGS Administrators, LLC ("CGS"); and
- First Coast Service Options, Inc. ("FCSO") (Palmetto, Noridian, WPS, Novitas, NGS, CGS, and FCSO are collectively referred to herein as the "MACs") (collectively, the MACs, Becerra, HHS, LaSure, and CMS are referred to herein as the "Government" or "Appellees").

The following parties, intervenors, and amici curiae currently appear before this Court:

- Appellant in this matter is Row 1 Inc. d/b/a/ Regenative Labs.
- Appellees are the following parties:
  - Becerra, solely in his official capacity as Secretary of the United States Department of Health and Human Services;
  - HHS;
  - LaSure, solely in her official capacity as Administrator of the Centers for Medicare and Medicaid Services;
  - CMS;
  - Palmetto;
  - Noridian;
  - WPS;

- Novitas;
- NGS;
- CGS; and
- FCSO.

- Amici Curiae, if any, are currently unknown.

Regenative is a Delaware corporation with a principal place of business in Pensacola, Florida. Regenative manufactures, markets, and distributes medical products containing human cells, tissues, or cellular or tissue-based products ("HCT/Ps"). There is no publicly held company that has a 10% or greater ownership in Regenative.

2. Rulings Under Review

The rulings at issue in this case are the United States District Court for the District of Columbia's final, appealable Order and accompanying Memorandum Opinion, both entered on January 12, 2023, at docket numbers 39 and 40, respectively, by Judge Amit. P. Mehta, Case No. 22-cv-718. The Memorandum Opinion and Order are reprinted in the Joint Appendix at JA216 and JA224.

3. Related Cases

Review of these rulings has not been sought previously in any court. The district court designated *StimLabs, LLC v. Becerra*, No. 22-cv-01988 (APM), 2022 WL 13840218 (D.D.C. Oct. 21, 2022) (granting motion to dismiss), *order corrected*

on denial of reconsideration, 2023 WL 183688 (D.D.C. Jan. 12, 2023), as a related case. The case name and number for this matter are *Row 1 Inc., d/b/a Regenative Labs v. Becerra*, No. 23-5020 (D.D.C.).

Respectfully submitted,

Date: May 3, 2023

/s/ Brian H. Pandya
Brian H. Pandya
DUANE MORRIS LLP
901 New York Ave. NW, Suite 700E
Washington, DC 20001
Tel: 202.776.7800
Email: BHPandya@duanemorris.com

Frederick R. Ball
DUANE MORRIS LLP
100 High Street, Suite 2400
Boston, MA 02110-1724
Tel: 857.488.4229
Email: FRBall@duanemorris.com

Robert M. Palumbos
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103-4196
Tel: 215.979.1111
Email: RMPalumbos@duanemorris.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Regulations

GLOSSARY

APA	Administrative Procedure Act
Becerra	Xavier Becerra
CGS	CGS Administrators, LLC
CMS	Centers for Medicare & Medicaid Services
FCSO	First Coast Service Options, Inc.
FDA	Food & Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HCT/P	Human Cells, Tissues, or Cellular or Tissue-based Products
HHS	Department of Health & Human Services
LaSure	Chiquita Brooks-LaSure
LCD	Local Coverage Determination
MAC	Medicare Administrative Contractor
NCD	CMS National Coverage Determination
NGS	National Government Services, Inc.
Noridian	Noridian Healthcare Solutions, LLC
Novitas	Novitas Solutions, Inc.
Palmetto	Palmetto GBA, LLC
PHSA	Public Health Service Act
TDL	Technical Direction Letter

WPS	Wisconsin Physicians Service Insurance Corporation

STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

Regenative pled subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361, and 1651. Joint Appendix ("JA") 113, at Am. Compl. ¶ 25. The district court held that it did not have subject matter jurisdiction. JA216, at Mem. Op. p. 1. That ruling is the subject of this appeal.

This Court has jurisdiction over the present appeal pursuant to 28 U.S.C. § 1291 as an appeal from a final, appealable Order of the United States District Court for the District of Columbia, dated January 12, 2023, that disposed of the causes of action in this matter. JA333. Regenative filed a timely notice of appeal on January 24, 2023. JA334.

STATEMENT OF THE ISSUES

1. Did the district court err by holding that it lacked subject matter jurisdiction because Regenative's causes of action arise under Section 405(h)?

2. Did the district court err by holding that the "no review at all" exception to Section 405(h) did not apply?

3. Did the district court err by holding that it lacked subject matter jurisdiction under the Mandamus Act, 28 U.S.C. § 1361, because Regenative's causes of action were not otherwise unreviewable procedural issues that are unrelated to the merits?

STATUTES AND REGULATIONS

The relevant statutes and regulations are reprinted in the Addendum to this Brief.

STATEMENT OF THE CASE

1. Statutory and Regulatory Background

This appeal involves parallel but decidedly distinct roles by two HHS agencies—the FDA and CMS. FDA regulates the manufacture, sale, marketing, and use of HCT/Ps and other biologic therapies pursuant to the PHSA. JA105, at Am. Compl. ¶ 2. The PHSA provides two separate regulatory pathways for HCT/Ps. JA105, at Am. Compl. ¶ 2. The first pathway includes HCT/Ps regulated solely under Section 361 of the PHSA (42 U.S.C. § 264). JA105, at Am. Compl. ¶ 2. The FDA promulgated four criteria to identify products subject to Section 361 regulation:

1. the HCT/P must be minimally manipulated;
2. the HCT/P must be intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
3. the manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, other than water, crystalloids, or a preserving, sterilizing, or storage agent provided such other article does not raise a new clinical safety concern; and
4. either:
    a. the HCT/P does not have a systemic effect and is not dependent on the metabolic activity of living cells for its primary function; or
    b. the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        i. is for autologous use;
        ii. is for allogeneic use in a first-degree or second-degree blood relative; or

iii. is for reproductive use.

21 C.F.R. § 1271.10(a). HCT/Ps that meet these criteria are referred to as Section 361 products and are exempt from licensing or pre-market approval from FDA. JA105, at Am. Compl. ¶ 2. Examples of Section 361 products include skin, tendons, cartilage, and connective tissues, including those found in the umbilical cord. JA106, at Am. Compl. ¶ 3. Industry has relied on these criteria for over two decades following notice-and-comment rulemaking the FDA undertook in 2001. JA105, at Am. Compl. ¶ 2; JA115, at Am. Compl. ¶ 37.

If a product fails to meet these criteria, the FDA regulates it as a "drug, device, or biological product" under either Section 351 (42 U.S.C. § 262) if a biologic product or under the FDCA if a drug. JA105, at Am. Compl. ¶ 2. Section 351 defines a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." JA116, at Am. Compl. ¶ 42 (quoting PHSA, Pub. L. No. 78-410, § 351, 58 Stat. 682, 702 (1944)). Such products signal greater safety risks that warrant premarket review and approval under Section 351, requiring clinical trials to demonstrate safety and efficacy in a process similar to that required for drugs regulated under the FDCA. JA116, at Am. Compl. ¶¶ 41, 43. FDA has the sole

authority to regulate and enforce the requirements imposed by Congress under Sections 361 and 351 of the PHSA. JA115, at Am. Compl. ¶ 37.

CMS administers the Medicare and Medicaid programs, which pay for care provided to beneficiaries using products regulated by the FDA. JA118, at Am. Compl. ¶ 56. CMS's role in overseeing these healthcare programs includes determining which healthcare claims get reimbursed based on a variety of factors, including whether the product is authorized for the prescribed purpose. Vital for this appeal, the CMS reimbursement determination does not include determining whether products meet or satisfy the applicable FDA regulations. JA118, at Am. Compl. ¶ 57 (citing Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286). Thus, when assessing claims, CMS's role is dependent upon FDA's role, not coextensive with it: FDA is the scientific authority that decides whether a product falls under the rubric of Section 361 or 351. CMS is neither authorized by Congress nor qualified by its agency expertise to make that decision, nor is it authorized to hold Section 361 products to more stringent Section 351 requirements

To carry out its claim administration role, CMS and HHS are statutorily authorized to enter into contracts with MACs, multi-state, regional contractors responsible for administering Medicare claims, making payments on claims, determining payment amounts, setting policy statements, and establishing LCDs, among other tasks. JA118, at Am. Compl. ¶ 58 (citing 42 U.S.C. § 1395kk-1).

2. Statement of Facts

Regenative is an American company that manufactures, markets, and distributes medical products containing HCT/Ps. JA105, at Am. Compl. ¶ 1. As relevant here, Regenative distributes AmnioText (formerly marketed as CoreText) and ProText, which consist of minimally manipulated Wharton's Jelly tissue. JA105, at Am. Compl. ¶ 1. Wharton's Jelly is a connective tissue found in the umbilical cord. JA105, at Am. Compl. ¶ 1.

Since beginning operations, Regenative has ensured that its products satisfy the elements required to be marketed, distributed, and regulated solely as Section 361 products, including registering with the FDA, listing its HCT/Ps with the FDA, and following legal and scientific guidance to ensure that these products meet the Section 361 criteria. JA105-JA106, at Am. Compl. ¶ 3. To date, the FDA—the entity with sole authority to designate Section 351 or 361 status—has not rejected or otherwise indicated any disagreement with the designation of Regenative's products as being regulated solely under Section 361. JA106, at Am. Compl. ¶ 3.

In order to facilitate reimbursement for the use of Regenative's product, CMS issued a Q-code (Q4246).[1] JA106, at Am. Compl. ¶¶ 3-4. In applying for the Q-

[1] CMS establishes Q-codes to identify products or services not identified by national HCPCS Level II codes in order to facilitate reimbursement. *See* Dep't of Health and Hum. Servs., Ctrs. For Medicare & Medicaid Servs., *Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures* (2022),

code, Regenative identified its products as Section 361 products and went through a number of steps and reviews. JA105-JA106, at Am. Compl. ¶ 3. CMS approved Regenative's application and properly deferred to FDA's regulatory authority regarding the proper regulatory pathway under which Regenative's products fell. JA106, at Am. Compl. ¶¶ 3-4. Since February 14, 2020, Regenative has sold its products as 361 products, and providers have received reimbursement from MACs under Q-code Q4246 for its coded products, AmnioText and ProText. JA106, at Am. Compl. ¶ 4.

However, in late 2021, Regenative became aware that the MACs were processing claims for its products differently, as some MACs were reimbursing claims for Regenative's products pursuant to Q4246, but others were denying claims for various reasons (which they often could not explain). JA106, at Am. Compl. ¶ 5. This practice continues today.

On or around February 8, 2022, Regenative learned of an email from one of the MACs stating that "CMS has temporarily frozen ALL biologics being billed with a Q code. There have been changes to the fees [*sic*] schedules and they are updating their billing platform. For that reason, claims are not being processed. To be clear,

---

https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.

they are NOT denied, they just are holding off adjudicating the claims so they have time to properly update." JA106-JA107, at Am. Compl. ¶ 6.

For the next few weeks, Regenative heard nothing further from that MAC or any other MAC. JA107, at Am. Compl. ¶ 7. However, in late February 2022, each of the MACs (in what Regenative believes was a coordinated effort orchestrated by CMS and HHS) released a statement, without adhering to statutorily required rulemaking procedures such as notice and comment, that each MAC will deny all claims for ***any*** amniotic and placental tissue products and will recoup payments for previous claims made between December 6, 2019, to the present (such statements, notices, subsequent automatic denials, and underlying policy are referenced herein as the "Policy"). JA107, at Am. Compl. ¶ 7.

The Policy did not acknowledge the regulatory distinction between Section 351 and Section 361 products. JA107, at Am. Compl. ¶ 7. The grounds for these Policy notices were apparently a misunderstanding of three random FDA statements issued between 2019 and 2021, none of which went through the formal FDA review process, and which discuss only those factors that relate to biologic cellular or tissue products regulated under ***Section 351***—not Section 361 products. JA108, at Am. Compl. ¶ 8. This misunderstanding could have been clarified had the Government adhered to its required notice-and-comment procedure, where manufacturers could

have clarified why Section 361 products should not be held to Section 351 requirements.

Ignoring the differences between these two regulatory pathways, CMS and the MACs have applied, and continue to apply, Section 351 approval requirements to Section 361 products. This conduct contravenes Congress' intent concerning these two pathways and exceeds the authority vested by Congress in the Government Appellees. JA107, at Am. Compl. ¶ 7. Indeed, one MAC's Policy notice provides that "any amniotic and/or placental derived products without Pre-Market Approval under section 351 of the [PHSA] and the [FDCA], along with their associated services will be denied." JA107, at Am. Compl. ¶ 7. Not only does this notice ignore the regulatory framework Congress enacted by ignoring that such products could receive Section 361 designations, but it also ignores the express language of NCDs, which cover Section 361 products and are binding on the MACs. JA107-JA108, at Am. Compl. ¶ 7.

The Government, in its motion to dismiss Regenative's original complaint, conceded that CMS issued a TDL to the MACs, purportedly "instructing them to deny claims for Medicare payment for ***manipulated*** amniotic and/or placental tissue biologics for injection," as well as a "follow-up [TDL]" on February 24, 2022, with specific instructions to, *inter alia*, deny any claims containing Regenative's CMS-approved Q4246 code, among others. JA109, at Am. Compl. ¶ 10 (emphasis added).

In response to Regenative's filing of the original complaint, on March 25, 2022, CMS and the MACs issued new TDL instructing "the MACs to remove system edits that automatically denied payment for amniotic and placental tissue product injections and to institute claim-by-claim review to determine whether a claim meets the reasonable and necessary criteria . . . ." JA109, at Am. Compl. ¶ 10. CMS's March 25, 2022 TDL expressly clarifies that "it is not intended by CMS, and shall not be construed, as a finding that any products are eligible for coverage or payment." JA109, at Am. Compl. ¶ 10.

Yet despite these TDLs, the Policy continues in full force behind the scenes if not publicly. JA110, at Am. Compl. ¶ 11. Although the MAC Policy statements have been removed from their websites, the automatic denial of Regenative's products remains the same. JA110, at Am. Compl. ¶ 11.

As a result of this unauthorized and improper rulemaking, where the Government required Section 361 products to meet Section 351 requirements, despite having no statutory basis for doing so and not giving notice-and-comment to stakeholders, Regenative has suffered and will continue suffer irreparable harm unless CMS and its MACs are enjoined from implementing this Policy. JA111, at Am. Compl. ¶ 12.

3. Procedural History

Regenative filed its Complaint against Appellees on March 15, 2022, simultaneously moving for a preliminary injunction to delay enforcement of the Policy. JA10; JA101. On March 25, 2022, CMS and the MACs allegedly rescinded the former Policy. JA109-JA110, at Am. Compl. ¶¶ 10-11. They then filed a notice of mootness and asked the district court to hold Regenative's motion for preliminary injunction in abeyance pending its determination of whether the court had subject matter jurisdiction. Consent Mot. to Hold Prelim. Inj. Mot. in Abeyance, Dkt. 12. On March 27, the district court granted the Government's motion to hold in abeyance Regenative's preliminary injunction motion. JA4-JA5. The Government moved to dismiss on June 21, 2022, arguing that the case was moot, that the district court had no subject matter jurisdiction, and that most of the defendants should be dismissed on grounds of immunity. Defs.' Mot. to Dismiss, Dkt. 17.

On July 12, 2022, Regenative filed an Amended and Verified Complaint that mooted the Government's motion to dismiss by explaining that in practice, the allegedly rescinded Policy remained in full effect, despite CMS and the MACs retracting the formal documents that initially established the Policy. JA104. The Government moved to dismiss the Amended and Verified Complaint on August 25, 2022. Defs.' Mot. to Dismiss, Dkt. 23. Regenative opposed that motion on September 22, 2022, and the Government filed a reply in further support of its

motion to dismiss on October 21, 2022. Pl.'s Opp'n to Defs.' Mot. to Dismiss, Dkt. 25; Reply in Further Supp. of Defs.' Mot. to Dismiss, Dkt. 32. Regenative then moved for an oral hearing on November 29, 2022, which the Government opposed with a response on December 13, 2022. Pl.'s Notice of Suppl. Authority and Mot. for Oral Hr'g on Defs.' Mot. to Dismiss, Dkt. 33-34; Resp. to Pl.'s Combined Notice of Suppl. Authority and Mot. for Oral Hr'g on Defs.' Mot. to Dismiss, Dkt. 35-36.

On January 12, 2023, without hearing or oral argument, the district court granted the Government's motion to dismiss, issuing a Memorandum Opinion and a final, appealable Order. JA216; JA333. Regenative filed a timely notice of appeal on January 24. JA334. The district court's January 12 Opinion and Order constitute the ruling presented for review in this appeal.

SUMMARY OF ARGUMENT

First, the district court erred by applying 42 U.S.C. § 405(h) to bar Regenative's causes of action. Section 405(h)'s prohibition against actions to "recover on any claim" under the Medicare Act applies to actions to recover, either directly or indirectly, monetary claims for reimbursement. This channeling provision does not apply to Regenative's causes of action, which seek to vindicate Regenative's interest in ensuring that CMS acts with procedural regularity in issuing new rules.

Second, even if Section 405(h) applied to Regenative's causes of action, the district court erred by holding that the "no review at all" exception to the channeling requirement is inapplicable. Regenative pled facts, which must be accepted as true at the motion to dismiss stage, establishing that it had no proxy access to the administrative appeals process. Further, at the Rule 12(b)(6) stage, Regenative is entitled to an inference based on the facts pled that no provider is incentivized to pursue the particular causes of action that Regenative has brought. Because CMS failed to engage in mandated notice-and-comment rulemaking, Regenative had no opportunity to provide comments on the Policy prior to implementation. Had CMS done so, it would have needed to provide a reasoned response to the concerns raised by Regenative in this lawsuit.

Third, the district court erred by holding that it therefore lacked subject matter jurisdiction under the Mandamus Act, 28 U.S.C. § 1361. Regenative's causes of action meet all three elements of the Mandamus Act, which alone is sufficient for subject matter jurisdiction. Further, no adequate proxy exists, because no proxies are sufficiently incentivized to bring the challenges that Regenative brings to CMS's procedural failures. Therefore, by dismissing Regenative's cause of action, the district court has granted CMS liberty to ignore the safeguards of the APA, as no entity exists to challenge its conduct.

ARGUMENT

Standard of Review

This Court "review[s] *de novo* the district court's grant of a motion to dismiss for lack of subject matter jurisdiction." *Al Janko v. Gates*, 741 F.3d 136, 139 (D.C. Cir. 2014); *see also Willner v. Dimon*, 761 F. App'x 1, 3 (D.C. Cir. 2019) ("This Court applies a *de novo* standard of review for a district court's . . . dismissal under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction."); *Nix v. Billington*, 448 F.3d 411, 414 (D.C. Cir. 2006) ("We review the District Court's determination that it lacks subject matter jurisdiction *de novo*."). Where, as here, "the Government has not disputed the facts relevant to jurisdiction, [this Court must] accept the Appellant's allegations as true and review only the district court's application of the law." *Al Janko*, 741 F.3d at 139; *see also Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir. 2002) ("We review the district court's dismissal of the complaint *de novo,* accepting the complaint's allegations as true for purposes of this appeal.").

1. The district court erred by holding that it lacked subject matter jurisdiction under the jurisdiction-stripping provisions of 42 U.S.C. § 405(h) where Regenative Labs did not "seek to recover on any claim arising under" the Medicare Act.

The district court erred in interpreting the statutory language of 42 U.S.C. § 405(h). The relevant portion of Section 405(h) states that "[n]o action against the United States, the [Secretary of Health and Human Services], or any officer or employee thereof shall be brought under Section 1331 or 1346 of title 28 to recover

on any claim arising under this subchapter." The district court's interpretation fails to give any meaning to the phrase "recover on any claim arising under this subchapter," which implies that not all causes of action are foreclosed.

The phrase "to recover on any claim" under the Medicare Act, by its plain language, relates to the individual processing of claims for monetary reimbursement for services or goods provided under the Medicare Act. It does not encompass causes of action like those brought by Regenative to vindicate an interest in procedural regularity. Indeed, Section 405 is titled: "Evidence, procedure, and certification ***for payments***." 42 U.S.C. § 405 (emphasis added).

Here, Regenative is not attempting to "recover on any claim" under the Medicare Act, nor is Regenative seeking any "payment" under the Medicare Act. By using such language, Congress intended for Section 405(h) to channel claims to recover reimbursement or payments under the Medicare Act, but it did not foreclose actions such as Regenative's that address agency conduct. An interpretation barring Regenative's causes of action here would render the phrase "to recover on any claim" mere surplusage with zero effect.

The first step in statutory interpretation is to look at the plain language of the statute. *See Aref v. Lynch*, 833 F.3d 242, 263 (D.C. Cir. 2016) ("[W]e nonetheless begin with the statute's plain language . . . ."); *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 297 (D.C. Cir. 2003) ("We begin, as always, with the plain language of

the statute in question."); *Nat'l Pub. Radio, Inc. v. FCC*, 254 F.3d 226, 230 (D.C. Cir. 2001) ("[S]tatutory language represents the clearest indication of Congressional intent . . . ."). Where "the plain language of the statute is clear, the court generally will not inquire further into its meaning." *Qi-Zhuo v. Meissner*, 70 F.3d 136, 140 (D.C. Cir. 1995) (citing *Norfolk & W. Ry. Co. v. American Train Dispatchers' Ass'n,* 499 U.S. 117, 128 (1991)).

Statutory interpretation requires "construe[ing] a statute so as to give effect to every clause and word." *Air Transp. Ass'n of Am., Inc. v. United States Dep't of Agric.*, 37 F.4th 667, 674 (D.C. Cir. 2022) (internal quotation marks omitted) (interpreting statutory language of "related" to "perform[] an important narrowing function"). Here, the plain language of Section 405(h) is limited to barring any action "to recover on any claim" under the Medicare Act. 42 U.S.C. § 405(h). The plain language of "recover[ing] on any claim" does not and cannot be reasonably interpreted to include Regenative's challenge to the procedural irregularity of the Policy.

The district court erred by relying upon *Shalala v. Illinois Council on Long Term Care, Inc.,* 529 U.S. 1 (2000). Unlike in this case, the plaintiffs in *Illinois Council* were Medicare providers seeking reimbursement—*i.e.*, seeking "to recover on a[] claim." *Illinois Council* did not establish a blanket ruling denying any causes of action. *Id.* And it could not possibly have altered the plain language of

Section 405(h), which is facially inapplicable to a procedural challenge to CMS's failure to adhere to its rulemaking requirements and to taking action outside of its statutorily provided authority.

The district court also cited *Heckler v. Ringer*—a case brought by Medicare beneficiaries that the court found was barred under Section 405(h) because the challenges to the methodology adopted by the Secretary were "inextricably intertwined" with the beneficiaries' claims for benefits. 466 U.S. 602, 615 (1984). Thus *Ringer*, like *Illinois Council*, ultimately involved an effort "to recover on a[] claim" for payment. Other Supreme Court cases involving the application of Section 405(h) similarly involve challenges to "reimbursement determination[s]" and parties who have "filed a claim for reimbursement." *See, e.g.*, *Your Home Visiting Nurse Servs. v. Shalala*, 525 U.S. 449, 456 (1999); *Ringer*, 466 U.S. at 609. Here, Regenative is a manufacturer challenging the procedural irregularities in CMS's shadow rulemaking. Regenative is not seeking, and could not seek, reimbursement or benefits, which is the only type of claim channeled by the statute.

The district court ignored that this Court has held that when a suit is brought to "vindicate an interest in procedural regularity, Section [405(h)] is not summoned into play." *Nat'l Assoc. of Home Health Agencies v. Schweiker*, 690 F.2d 932, 937 (D.C. Cir. 1982) ("*NAHHA*") (quoting *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070, 1080 (D.C. Cir. 1978)). In *NAHHA*, an association of home health

agencies challenged HHS's implementation of administrative instructions relating to Medicare reimbursement determinations and payments on several bases, including that HHS failed to adhere to the notice-and-comment requirements. *Id.* HHS argued that the challenge was barred by Section 405(h). This Court, however, found that Section 405(h) "bars only actions brought to 'recover on any claim' arising under the Medicare Act." *Id.* Accordingly, this Court "h[e]ld that section 405(h) does not preclude claims challenging the Secretary's compliance with the APA." *Id.* That should have ended the inquiry here.

Illinois Council did not overrule *NAHHA* or *Humana*, nor has this Court held as such. To the extent the Government argues that *Ringer* overruled *NAHHA* by refusing to distinguish between "substantive" and "procedural" objections, it misconstrues the ruling and ignores that the *Ringer* holding was based on a finding that plaintiff's claim was not "anything more than, at bottom, a claim that they should be paid for their [services rendered]" and that their "procedural" causes of action were "inextricably intertwined" with a "substantive" claim for reimbursement of benefits. *Ringer*, 466 U.S. at 614. This Court's ruling in *Ringer* is easily distinguished from *NAHHA*, where the Court held that "actions like the present one are brought to challenge secretarial action unrelated to reimbursement disputes." 690 F.2d at 941. The district court's interpretation of Section 405(h) was thus more restrictive than the language Congress enacted, more restrictive than the

interpretation in *Illinois Council*, and contrary to this Court's holdings in *NAHHA* and *Humana*.

The Government does not and cannot claim that Regenative can avail itself of the administrative appeals process. It is not an intended beneficiary of that process and has no right to participate in it or method for doing so. *See* 42 C.F.R. §§ 405.906(a)-(b). Under the broad interpretation of the district court, Regenative is effectively denied its right to challenge an agency decision made in contravention of the notice-and-comment requirements of the APA, even though that decision directly affects Regenative's interests.[2] Had CMS complied with the APA and engaged in notice-and-comment rulemaking, Regenative could have submitted comments to which CMS would have needed to respond in a comprehensive and cogent manner before implementing its Policy. Instead, the district court's decision allows for an agency to reject its statutory responsibilities under the APA and then to preclude a challenge to that failure brought by an entity alleging harm.

The Government has taken the position that Regenative's causes of actions are barred by Section 405(h) because the Medicare Act provides "both the standing and substantive basis" for the claim. Reply in Further Supp. of Defs.' Mot. to Dismiss, Dkt. 32, at p. 4 (quoting *Your Home Visiting Nurse Servs.*, 525 U.S. at 456).

[2] The Government does not argue that Regenative has not pled a particularized harm and therefore lacks standing.

This argument, however, ignores that a procedural harm can be the ultimate basis for standing even where, as the Government argues, the concrete injury of the procedural harm is tied to a reimbursement denial under the Medicare Act. *See, e.g.*, *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 112-13 (D.D.C. 2009) (finding standing based on procedural harm where a drug manufacturer sued HHS and CMS to challenge their designation of its clotting factor as a multiple-source drug, even though the concrete injury underlying that procedural harm was a reimbursement issue); *Akebia Therapeutics, Inc. v. Becerra*, 548 F. Supp. 3d 274, 276 (D. Mass. 2021) (finding standing based on procedural harm where a drug manufacturer sued to enjoin a CMS decision that eliminated Medicare Part D coverage for the manufacturer's drug, even though the concrete injury for that procedural harm was a reimbursement issue).

Moreover, Regenative's causes of action include that CMS and the MACs failed to adhere to the notice-and-comment requirement of the *APA*. 5 U.S.C. § 553(b). This procedural requirement in the APA is separate and apart from the procedural requirements under the Medicare Act and gives separate and independent standing and a substantive basis for Regenative's causes of action.[3] In addition,

[3] Relying upon *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), the Government argued that the notice-and-comment requirement arises under the Medicare statute. Reply in Further Supp. of Defs.' Mot. to Dismiss, Dkt. 32, at p. 6. However, the Government ignores completely the notice-and-comment requirement under the APA, which the Court in *Allina* recognized as being separate from and in

although CMS manages only Medicare and Medicaid reimbursement, the Policy (enacted without notice and comment) has effectively resulted in Regenative's products being perceived as marketed and promoted illegally because of CMS's contention that the proper regulatory pathway is Section 351, not Section 361, thus causing non-Medicare/Medicaid, self-pay, and cash payment providers to stop using Regenative's products. Accordingly, Regenative's injury is not one that can be attributed wholly to the Medicare Act.

Section 405(h) does not preclude subject matter jurisdiction for Regenative's causes of action asserting that CMS failed to follow statutorily required notice-and-comment procedures and that CMS exceeded its statutory authority.

2. The district court erred by refusing to apply an exception to 42 U.S.C. § 405(h)'s jurisdiction-stripping provisions under the facts pled in this case.

Even if Section 405(h) did apply to Regenative's causes of action (it does not), the district court's ruling that Regenative's challenges do not fall within the exceptions to Section 405(h)'s channeling requirement is directly contradicted by this Court's opinion in *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 709 (D.C. Cir. 2011). The district court ignores that a plaintiff may obtain judicial review of regulations where the hardship "turns what appears to be simply a

addition to the Medicare Act requirement for notice and comment. *Allina Health Servs.*, 139 S. Ct. at 1808-09, 1811-12.

channeling requirement into *complete* preclusion of judicial review." *Id.* at 712 (emphasis added). Instead of applying this Court's holding in *Council for Urological Interests*, the district court elected to misapply *Illinois Council*, resulting in complete preclusion of review of Regenative's causes of action.

Important policy considerations serve as the basis for the *Illinois Council* exception. Contrary to the district court's ruling, this Court has noted that "the Supreme Court has understood section 405(h) as having only channeling force, not, as the government would have it, foreclosing force." *Id.* at 709 (citing *Illinois Council*, 529 U.S. at 19). This Court adheres to the Supreme Court's "'strong presumption that Congress intends judicial review of administrative action' and that 'judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress[,' and t]o overcome this presumption, the government bears a 'heavy burden.'" *Id.* at 708-09 (2011) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). Indeed, this Court has held that there is "no 'clear and convincing evidence,' in the statute's language or structure indicating that Congress deliberately intended to completely bar non-providers from seeking review of regulations that target them directly." *Id.* at 711 (internal citations omitted). Nonetheless, the district court effectively applied Section 405(h) to foreclose Regenative, a non-provider

directly affected by CMS's improper rulemaking, from accessing its right to judicial review.

This Court has held that a plaintiff qualifies for the *Illinois Council* exception "not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court." *Council for Urological Interests*, 668 F.3d at 712. "[T]he *Illinois Council* inquiry is fundamentally a practical one," and a court should analyze "factors that speak to a potential proxy's willingness and ability to pursue the plaintiff's [particular] claim." *Id.*

Here, Regenative brings three causes of action for declaratory and injunctive relief: (1) the Policy is arbitrary and capricious; (2) CMS and the MACs' agency action exceeded its statutory authority; and (3) CMS and the MACs failed to follow requisite rulemaking procedures, foregoing notice-and-comment obligations.

Here, as alleged, no provider is adequately incentivized to bring *these particular causes of action* via the administrative process. Regenative has alleged and/or stated (1) that providers will simply choose not to purchase and use Regenative's products that CMS and the MACs state are "illegally marketed," improperly used, and not "safe or effective," (2) that providers will use alternative treatments instead of Regenative's products, (3) that it is impossible for providers to submit reimbursement claims due to the MACs' required documentation, and (4) that Regenative has not sought to have a provider assign its claim because of the

possible implications of the Anti-Kickback Statute. *See* JA184-JA215, at Am. Compl. Exs. C-E (repeating the "illegally marketed" language across numerous documents); JA230, at Am. Complaint ¶ 123; *see also Akebia*, 548 F. Supp. 3d at 286 n.15 (D. Mass 2021) ("As Akebia points out, the Government could view an attempt by Akebia to serve as an assignee or representative for a participant as a violation of the federal anti-kickback statute . . . The Government has not responded to this argument, nor has it anywhere suggested that Akebia could act as a representative or assignee."). At this stage, Regenative's allegations must be accepted as true.

From a practical perspective, no provider is incentivized to pursue the three particular injunctive and declaratory causes of action that Regenative has brought. *See Council for Urological Interests*, 668 F.3d at 709 (holding that a court should analyze "factors that speak to a potential proxy's willingness and ability to pursue the plaintiff's [particular] claim"). Providers would not even know that CMS and the MACs have enacted this shadow rule because CMS and the MACs claim to have rescinded the Policy, despite full adherence to the Policy behind the scenes. A provider cannot challenge what it does not know exists.

And if any provider were aware of the shadow Policy and incentivized to bring a claim, it would, practically, be only a claim for reimbursement under the "medically and reasonably necessary" standard of care—not a lawsuit to seek

injunctive relief against CMS and the MACs to enforce their statutory obligations. *See Regeneron Pharm., Inc. v. United States Dep't of Health & Hum. Servs*., 510 F. Supp. 3d 29, 44 (S.D.N.Y. 2020) (holding "that there are no adequate proxies to advance Plaintiff's individual claim" where providers have alternatives and where any providers would not be able to seek the injunctive relief plaintiff seeks). Aside from its *ipse dixit* opinion that adequate proxies exist, the Government has pointed to nothing to contradict the allegations that no adequately incentivized proxy exists to bring Regenative's particular causes of action. According to the district court's interpretation of Section 405(h), Regenative's rights hinge upon a hope and a prayer that some unknown provider will pursue, not just reimbursement for his particular claim, but the three specific causes of action that Regenative has brought concerning CMS and the MACs' failure to adhere to their rulemaking procedural requirements.

The district court relied on *RICU LLC v. United States Department of Health & Human Services*, 22 F.4th 1031 (D.C. Cir. 2022), in holding that adequate proxies exist to assert Regenative's claims. JA221, at Mem. Op. p. 6. However, the district court's reliance on *RICU* is misplaced and actually illustrates why the *Illinois Council* exception should apply to Regenative here. In *RICU*, notice-and-comment rulemaking had been followed. *Id.* at 1033-34 (citing Medicare and Medicaid Programs, 85 Fed. Reg. 19,230 (Apr. 6, 2020); Medicare Program, 85 Fed. Reg. 84,472 (Dec. 28, 2020)). The Court in *RICU* acknowledged that the *Illinois Council*

exception applies where "adherence to the channeling requirement effectively would cut off judicial review under the Medicare Act." *Id.* at 1038. The Court held, however, that because plaintiff brought a "general claim that its [client's] services are eligible for Medicare reimbursement," plaintiff's client hospitals were adequate proxies. *Id*. at 1039. The plaintiff in *RICU* had effectively sought a pre-determination of eligibility for reimbursement by its client hospitals that used its services. *Id*. Based on that particular claim, the Court held that adequate proxies exist. *Id.* Of course, RICU's clients would be adequate proxies to seek reimbursement for services they provided. Here, Regenative does not bring a claim that its customers "are eligible for Medicare reimbursement." Rather, Regenative challenges CMS and the MACs' failure to follow notice-and-comment procedural requirements. No adequate proxy exists to bring this particular claim.

In *Council for Urological Interests*, the Court held that the plaintiff had no adequate proxy, finding that it was the government who had "failed to counter the []allegations with, for instance, affidavits from hospitals attesting to their incentives or intent to pursue an administrative challenge." 668 F.3d at 713. Here, the district court appears to flip this analysis on its head. The district court erred in finding, without any factual support provided by the Government, that Regenative was required to "establish[] that it has attempted but cannot secure a provider to designate them as a[n] 'appointed representative' . . . to pursue administrative review of a

claim." JA221, at Mem. Op. p. 6. The district court also erred in finding that Regenative failed to show "that there are no existing providers of its products that have pending claims before CMS." JA221, at Mem. Op. p. 6. It is not relevant whether a provider has ***any*** pending claims before CMS; it is instead relevant whether a provider is pursuing or is willing to pursue the three "particular claim[s]" asserted by Regenative here. *See Council for Urological Interests*, 668 F.3d at 713.

Here, the Policy is not merely a "denial of reimbursement" for Regenative; rather, CMS and the MACs have effectively rendered Regenative's products unmarketable. As alleged in the Amended Complaint, the Policy has the effect of eliminating the FDA's Section 361 regulatory pathway and classifying Regenative's products as Section 351 products. JA122-JA123, at Am. Compl. ¶¶ 84-88. Regenative has not applied, nor has it been approved by the FDA, to sell its products under the Section 351 regulatory pathway because it is not a Section 351 product; therefore, the Policy is effectively holding, without adhering to procedural requirements, that Regenative has been manufacturing and selling its products without proper regulatory clearance. Regenative's causes of action in this matter seek to rectify this injury that is specific to Regenative, so this is certainly not a situation in which a provider seeking reimbursement would be sufficiently incentivized to assert the particular causes of action asserted by Regenative here. The Policy also negatively affects Regenative's ability to sell its products to non-

Medicare/Medicaid, self-pay, or cash payment providers. There is no administrative appeals process available with respect to this particular injury to Regenative.

In addition, here, as in *Council for Urological Interests*, the Government has provided no affidavits from providers attesting to their incentives or intent to pursue an administrative challenge based on the same causes of action set forth in Regenative's Amended Complaint. The district court's reversal, heightening, and misconstruing of the burden (requiring Regenative to establish with evidence that there exist no incentivized proxies) is contradictory to *Council for Urological Interests* and the policy behind the *Illinois Council* exception. Regenative has alleged that providers will now simply no longer use Regenative's products, thus providing for no future potential proxies through which Regenative's particular causes of action could be raised with CMS. Accordingly, the district court's refusal to apply an exception to 42 U.S.C. § 405(h)'s jurisdiction-stripping provisions under the facts pled in this case should be reversed.

The district court also erred by relying on the fact that the plaintiffs in *StimLabs* were providers. Regenative is entitled to have a motion to dismiss its Amended Complaint be decided on the allegations in its own Amended Complaint, not those of a wholly separate and unrelated matter and set of parties. On a motion to dismiss, a court must "accept[] the allegations of the complaint as true" and draw all inferences in favor of the nonmoving party. *Banneker Ventures, LLC v. Graham*,

798 F.3d 1119, 1129 (D.C. Cir. 2015). Here, Regenative alleged that no adequate proxy is sufficiently incentivized and willing to assert the particular causes of action Regenative asserts, and it has stated that the Anti-Kickback Statute would in fact preclude Regenative from recruiting any such proxy.

Accordingly, the district court erred in refusing to apply the *Illinois Council* exception to 42 U.S.C. § 405(h)'s jurisdiction-stripping provisions under the facts pled in this case, and therefore, the district court's order should be reversed.

3. The district court erred by holding that it lacked subject matter jurisdiction under the Mandamus Act, 28 U.S.C. § 1361

The district court acknowledged that mandamus jurisdiction is available under 28 U.S.C. § 1361. *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813 (D.C. Cir. 2001) ("[T]his court has previously determined that § 1361 jurisdiction is not barred [by Section 405(h)], joining the virtual unanimity of circuit courts."). The district court, however, erred in its application of the mandamus jurisdiction doctrine. The district court has mandamus jurisdiction here because Regenative can show: (1) a clear and indisputable right to relief; (2) that CMS is violating a clear duty to act; and (3) that no adequate alternative remedy exists. *Am. Hospital Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) ("*AHA*").

First, Regenative has a clear and indisputable right to relief to insist that CMS and the MACs follow the required rulemaking procedure. *Id.* at 183 (holding that where the "statute imposes a clear duty on the Secretary of [HHS] to comply with

statutory [requirements], that the statute gives the Association a corresponding right to demand that compliance").

Second, CMS had a clear statutory duty to promulgate regulations following the required notice-and-comment procedure. The statute is full of provisions requiring substantive rulemaking procedures to be followed:

> The Secretary *shall prescribe* such regulations as may be necessary . . . .

42 U.S.C. § 1395hh(a)(1)

> No rule, requirement, or other statement of policy that established or changes a legal standard . . . *shall take effect* unless it is promulgated by the Secretary . . . .

42 U.S.C. § 1395hh(a)(2).

> The Secretary *shall establish and publish* a regular timeline for the publication of final regulations . . . .

42 U.S.C. § 1395hh(a)(3)(A).

> [B]efore issuing in final form any regulation under subsection (a), the Secretary *shall provide* for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

42 U.S.C. § 1395hh(b)(1).

> The Commissioner . . . *shall adopt* reasonable and proper rules and regulations to regulate and provide for the nature and extent of proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

42 U.S.C. § 405(a). As this Court has held, Congress' consistent use of the typically mandatory "shall" demonstrates that CMS had a clear duty to follow the required

rulemaking process, including notice-and-comment. *See AHA*, 812 F.3d at 190. Regenative requested that the district court issue a writ of mandamus ordering CMS and the MACs to comply with the administrative rulemaking procedures required under the APA. Mandamus relief is available here, where CMS is violating a clear duty to act.

Third, Regenative has no alternative adequate remedy available to it because it has no access to the administrative appeals process. Judicial relief is the only option open to Regenative.

Under the district court's ruling, Regenative would be barred from mandamus jurisdiction for the same reason it is barred from Section 405(h) jurisdiction—a failure to channel claims through the administrative process—thus stripping the mandamus jurisdiction doctrine of any teeth or utility. However, exhausting the administrative process is not a prerequisite to jurisdiction for causes of action challenging failures of CMS to follow required administrative procedures. *See Helomics Corp. v. Burwell*, No. CV 16-546 (RMC), 2016 U.S. Dist. LEXIS 47803, at *14 (D.D.C. April 8, 2016) (rejecting defendants' argument that plaintiff failed to exhaust the administrative process, because plaintiff's claim "involves a challenge to [a MAC's] alleged failure to follow the required regulatory process" when it issued an LCD without a proper notice and comment period). The court in *Helomics* correctly recognized that "Section 405(h) only bars actions 'brought under section

1331 or 1346,'" and "[t]here is no reference to actions invoking mandamus jurisdiction under § 1361 or to procedural challenges to an LCD." *Id.*

The district court quoted *Wolcott v. Sebelius*, 635 F.3d 757 (5th Cir. 2011), for the proposition that mandamus jurisdiction is available "to review otherwise unreviewable procedural issues" that are "unrelated to the merits." JA331, at Mem. Op. 7 (quoting *Wolcott*, 635 F.3d at 765-66). The district court continues in its analysis, finding that "[Regenative's] procedural claims rest on [its] merits contention that CMS in fact has changed its coverage policy," and therefore, "mandamus jurisdiction is not appropriate." JA222, at Mem. Op. p. 7. The district court, however, omitted a key portion of the *Wolcott* quote—that mandamus jurisdiction is available where it is "unrelated to the merits of the benefits claim." *Wolcott*, 635 F.3d at 765-66 (internal quotation marks omitted). Here, Regenative has not brought, and importantly *cannot* bring, a "benefits claim." Regenative's causes of action relate solely to unreviewable procedural issues and not to any "benefits claim."

There are several cases in this Circuit, similar to the present action, in which a district court granted mandamus jurisdiction where a plaintiff asserted procedural causes of action unrelated to the merits. In *Samaritan Health Center v. Heckler*, the court found mandamus jurisdiction to order HHS to implement regulations that would determine whether plaintiffs (a group of hospitals) would receive larger

Medicare payments. 636 F. Supp. 503, 508-509, 511 (D.D.C. 1985) ("[P]laintiffs' [procedural] claim is not inextricably intertwined with a claim for benefits."). In *Cockrum v. Califano*, the district court found mandamus jurisdiction to order HHS to make a decision on benefits claims that plaintiffs (Medicare patients) had appealed. 475 F. Supp. 1222, 1225, 1229, 1230-31 (D.D.C. 1979) ("These [procedural] claims are obviously collateral to any substantive determination."). The district court misapplies *Wolcott*, and mandamus jurisdiction is available to Regenative here.

Further, in its Opinion, the district court provides no analysis of Regenative's causes of action, instead merely cross-referencing the district court's opinion in *StimLabs*: "For the reasons set forth in *StimLabs*, Plaintiff's procedural claims rest of Plaintiff's merits contention that CMS in fact has changed its coverage policy." JA222, at Mem. Op. p. 7. Not only do Regenative's procedural causes of action ***not*** relate to the merits of any benefits claim, but Regenative's causes of action are different than those alleged by the plaintiffs in *StimLabs*. The two actions are not related, and although they reference the same Policy, the facts and allegations of each case are unique, as set forth herein. In addition, in the *StimLabs* opinion, the district court issues another blanket statement that "[a]s 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."

StimLabs, 2022 WL 13840218, at *8. Regenative is unable to decipher how its causes of actions could be construed as being related to the merits of a benefits claim—and the simple answer is that they are not.

Under the district court's interpretation of mandamus jurisdiction in this context, CMS would be free to issue shadow rules and policies, without notice and comment or any other procedural safeguard, that result in businesses shutting down and patients losing access to vital care. The district court's interpretation would insulate CMS to act without following the Congressionally mandated rulemaking safeguards, particularly where, as here, a manufacturer cannot directly challenge the rule via the administrative process and where no adequate proxy exists sufficiently incentivized to bring the very challenge to the procedural failures brought by Regenative here.

Finally, this Court has held that mandamus jurisdiction is available where there exist "compelling . . . equitable grounds." *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005). Here, CMS and the MACs cannot be allowed to abuse the Section 405(h) channeling provision to issue shadow rules that substantively change legal standards for reimbursement while completely ignoring their statutory obligations with respect to notice-and-comment requirements. They must be held to strict compliance with their statutory obligations for the process of rulemaking, and they cannot hide behind the veil of Section 405(h) to act contrary

to Congress' statutory requirements. Indeed, mandamus jurisdiction exists to address precisely this kind of exceptional circumstance.

Accordingly, the district court erred in holding that it did not have jurisdiction to issue a writ of mandamus ordering CMS and the MACs to comply with the administrative rulemaking procedures required under the APA.

CONCLUSION

The dismissal order of the district court should be vacated and the case remanded for further proceedings.

Respectfully submitted,

Date: May 3, 2023

/s/ Brian H. Pandya
Brian H. Pandya
DUANE MORRIS LLP
901 New York Ave. NW, Suite 700E
Washington, DC 20001
Tel: 202.776.7800
Email: BHPandya@duanemorris.com

Frederick R. Ball
DUANE MORRIS LLP
100 High Street, Suite 2400
Boston, MA 02110-1724
Tel: 857.488.4229
Email: FRBall@duanemorris.com

Robert M. Palumbos
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103-4196
Tel: 215.979.1111
Email: RMPalumbos@duanemorris.com

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because it contains 7,951 words, excluding the parts of the brief exempted by Circuit Rule 32(e)(1).

This brief complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

/s/ Brian H. Pandya

CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2023, I served a true and correct copy of the foregoing on all counsel of record in this action via ECF.

/s/ Brian H. Pandya

Addendum

Table of Contents

Statutes

Regulations

5 U.S.C. § 553

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved--

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include--

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply--

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except--

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

28 U.S.C. § 1361

§ 1361. Action to compel an officer of the United States to perform his duty

The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff.

42 U.S.C. § 405(a)

§ 405. Evidence, procedure, and certification for payments

(a) Rules and regulations; procedures

The Commissioner of Social Security shall have full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this subchapter, which are necessary or appropriate to carry out such provisions, and shall adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

42 U.S.C. § 405(h)

§ 405. Evidence, procedure, and certification for payments

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. §§ 1395hh(a)(1)-(a)(3)(A)

§ 1395hh. Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

42 U.S.C. § 1395hh(b)(1)

§ 1395hh. Regulations

(b) Notice of proposed regulations; public comment.

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

21 C.F.R. § 1271.10(a)

§ 1271.10. Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?

(a) An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:

(1) The HCT/P is minimally manipulated;

(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;

(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

(4) Either:

(i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

(ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:

(a) Is for autologous use;

(b) Is for allogeneic use in a first-degree or second-degree blood relative; or

(c) Is for reproductive use.

42 C.F.R. § 405.906

§ 405.906. Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews

(a) Parties to the initial determination. The parties to the initial determination are the following individuals and entities:

(1) A beneficiary who files a claim for payment under Medicare Part A or Part B or has had a claim for payment filed on his or her behalf, or in the case of a deceased beneficiary, when there is no estate, any person obligated to make or entitled to receive payment in accordance with part 424, subpart E of this chapter. Payment by a third party payer does not entitle that entity to party status.

(2) A supplier who has accepted assignment for items or services furnished to a beneficiary that are at issue in the claim.

(3) A provider of services who files a claim for items or services furnished to a beneficiary.

(4) An applicable plan for an initial determination under § 405.924(b)(16) where Medicare is pursuing recovery directly from the applicable plan. The applicable plan is the sole party to an initial determination under § 405.924(b)(16) (that is, where Medicare is pursuing recovery directly from the applicable plan).

(b) Parties to the redetermination, reconsideration, proceedings on a request for hearing, and Council review. The parties to the redetermination, reconsideration, proceedings on a request for hearing, and Council review are—

(1) The parties to the initial determination in accordance with paragraph (a) of this section, except under paragraph (a)(1) of this section where a beneficiary has assigned appeal rights under § 405.912;

(2) A State agency in accordance with § 405.908;

(3) A provider or supplier that has accepted an assignment of appeal rights from the beneficiary according to § 405.912;

(4) A non-participating physician not billing on an assigned basis who, in accordance with section 1842(l) of the Act, may be liable to refund monies collected for services furnished to the beneficiary because those services were denied on the basis of section 1862(a)(1) of the Act; and

(5) A non-participating supplier not billing on an assigned basis who, in accordance with sections 1834(a)(18) and 1834(j)(4) of the Act, may be liable to refund monies collected for items furnished to the beneficiary.

(c) Appeals by providers and suppliers when there is no other party available. If a provider or supplier is not already a party to the proceeding in accordance with paragraphs (a) and (b) of this section, a provider of services or supplier may appeal an initial determination relating to services it rendered to a beneficiary who subsequently dies if there is no other party available to appeal the determination. This paragraph (c) does not apply to an initial determination with respect to an applicable plan under § 405.924(b)(16).

[ORAL ARGUMENT NOT SCHEDULED]

No. 23-5020

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Row 1 Inc., d/b/a Regenative Labs,

Plaintiff-Appellant,

v.

Xavier Becerra, Secretary of Health and Human Services, solely in his official capacity, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia

BRIEF FOR APPELLEES

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ABBY C. WRIGHT
CAROLINE D. LOPEZ
Attorneys, Appellate Staff
Civil Division, Room 7535
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-4825

Of Counsel:

SAMUEL R. BAGENSTOS
General Counsel

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation

JULLIA CALLAHAN BRADLEY
Attorney

U.S. Department of Health and Human Services

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

The plaintiff-appellee in this case is Row 1 Inc. d/b/a Regenative Labs.

The defendant-appellees in this case are Xavier Becerra, solely in his official capacity as Secretary of the United States Department of Health and Human Services; the United States Department of Health and Human Services; Chiquita Brooks-LaSure, solely in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; the Centers for Medicare & Medicaid Services; Noridian Healthcare Solutions, LLC; Wisconsin Physicians Service Insurance Corporation; Novitas Solutions, Inc.; National Government Services Inc.; CGS Administrators, LLC; Palmetto GBA, LLC; and First Coast Service Options, Inc.

There were no *amici* in district court.

B. Rulings Under Review

Plaintiff-appellant has appealed the January 12, 2023, memorandum and order granting defendants-appellees' motion to dismiss for lack of subject-matter jurisdiction (Dkt. Nos. 39, 40). The rulings were issued by the

Honorable Amit P. Mehta in No. 22-cv-718. The Memorandum Opinion and Order are reprinted in the Joint Appendix at JA 216 and JA 224.

C. Related Cases

The district court designated *StimLabs, LLC v. Becerra*, No. 22-cv-01988 (APM), 2022 WL 13840218 (D.D.C. Oct. 21, 2022) (granting motion to dismiss), *order corrected on denial of reconsideration*, 2023 WL 183688 (D.D.C. Jan. 12, 2023), as a related case. We are unaware of any other related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

/s/ Caroline D. Lopez
CAROLINE D. LOPEZ
Counsel for Appellees

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulations:

Other Authorities:

GLOSSARY

APA	Administrative Procedure Act
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
HCT/Ps or HCT/P products	Human Cells, Tissues, or Cellular or Tissue-Based Products
HHS	Department of Health and Human Services
JA	Joint Appendix

STATEMENT OF JURISDICTION

Plaintiff, Row 1 Inc., d/b/a Regenative Labs (Regenative), invoked the district court's jurisdiction under 28 U.S.C. §§ 1331, 1361, and 1651. Joint Appendix (JA) 113, ¶ 25. The district court granted the government's motion to dismiss Regenative's suit for lack of subject-matter jurisdiction on January 12, 2023. JA 216-24. Regenative filed a timely notice of appeal on January 24, 2023. JA 225. This Court has appellate jurisdiction under 28 U.S.C. § 1291

STATEMENT OF THE ISSUES

In February 2022, the Centers for Medicare & Medicaid Services (CMS) issued technical direction letters to its Medicare Administrative Contractors (Medicare contractors). Regenative claims that these letters should have been issued through notice-and-comment rulemaking and therefore improperly instructed Medicare contractors to automatically deny reimbursements for certain products containing human cells, tissues, or cellular or tissue-based products (HCT/Ps or HCT/P products), including those manufactured by Regenative. Although CMS rescinded these earlier letters in March 2022 and instructed Medicare contractors to instead evaluate claims under the reasonable and necessary standard on a case-by-case basis, including by reopening any prior claim denials issued under the original instructions, Regenative asserts that Medicare contractors are still applying the instructions

in the February letters to automatically deny reimbursements for its products. The questions presented are the following:

1. Whether the district court correctly concluded that it lacks subject-matter jurisdiction over Regenative's claims for declaratory and injunctive relief because they arise under the Medicare statute but were not presented to the agency.

2. Whether the district court correctly concluded that it lacks subject-matter jurisdiction over Regenative's mandamus claim because Regenative did not satisfy the threshold requirements for mandamus.

3. Whether, in the alternative, Regenative's suit is moot because CMS has rescinded the earlier instructions to its Medicare contractors and directed them to evaluate claims under the reasonable and necessary standard on a case-by-case basis, including by reopening any prior denials issued under the original instructions.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory Background

1. The Medicare Statute's Reasonable and Necessary Requirement

The Medicare program provides federally funded health insurance for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq.* CMS, a component of the Department of Health and Human Services (HHS), administers the Medicare program.

Medicare only pays for services and products that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(1). If the Secretary, or his designee, determines that the product or service was not necessary and reasonable in the context of a particular claim, the statute mandates that "no payment may be made." 42 U.S.C. § 1395y(a). To justify payment for items and services under Medicare Part B, a physician, supplier, or beneficiary must submit a claim for reimbursement. *Id.* § 1395y(e); 42 C.F.R. § 424.5(a)(5), (6).

CMS contracts with private entities, known as Medicare Administrative Contractors, to administer the Medicare program. 42 U.S.C. § 1395kk-1; *id.* § 1395u(a); 42 C.F.R. § 421.400. These entities provide the first step in processing Medicare claims and ensure that payments meet the coverage

requirements of the Medicare statute, including that the particular products and services billed satisfy the reasonable and necessary requirement. 42 U.S.C. § 1395y(a)(1)(A

Program beneficiaries or their assignees who are dissatisfied with a Medicare contractor's reimbursement determination have several layers of administrative review available to them. 42 U.S.C. § 1395ff; 42 C.F.R. §§ 405.906(a)(2), 405.912. They can first request a redetermination review by the same contractor, 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940; and then can request "reconsideration" by a qualified independent contractor, *see* 42 U.S.C. § 1395ff(b)(l)(A), (c); 42 C.F.R. § 405.960. For claims that satisfy the statutory amount-in-controversy requirement, a still dissatisfied claimant may request a hearing, "as is provided in [42 U.S.C. §] 405(b)," before an administrative law judge. 42 U.S.C. § 1395ff(b)(l)(A), (E), (d)(l); 42 C.F.R. § 405.1002. The administrative law judge's decision may be reviewed by the Medicare Appeals Council of the Departmental Appeals Board. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100.

To guide the application of the reasonable and necessary requirement during this administrative process, the Secretary may establish "reasonable and necessary" coverage standards through formal regulations. 42 U.S.C. §§ 1395y(a)(1)(A), 1395ff(a)(1), 1395hh. The Secretary may also issue binding

National Coverage Determinations "with respect to whether or not a particular item or service is covered nationally." *Id.* § 1395ff(c)(3)(B)(ii)(I), (f)(1)(B); *see also id.* § 1395y(a); 42 C.F.R. §§ 400.202, 405.1060(a)(4).The Secretary may also issue technical direction letters addressing coverage and payment issues to Medicare contractors. *Cf.* CMS, *General Information, Eligibility, and Entitlement Manual*, ch. 7, § 50, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ge101c07.pdf ("Contractors shall . . . comply with all issued Technical Direction Letters."). In the absence of a binding national policy, such as a regulation or a National Coverage Determination, coverage decisions are made by Medicare contractors, which may issue a local coverage determination, or use a claim-by-claim adjudicatory model. *See* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II), (f)(2)(B); 42 C.F.R. §§ 400.202, 405.1062; Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services, 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001).

2. The Medicare Statute's Channeling Provisions

The Medicare statute provides a highly "reticulated statutory scheme, which carefully details the forum and limits of review" of all claims arising under Medicare. *Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 675 (1986); 42 U.S.C. §§ 405(h), 1395ii (incorporating Section 405(h) into the

Medicare statute). In general, it provides that "[n]o action against . . . the [Secretary] shall be brought . . . to recover on any claim arising under [the Medicare statute]" except as provided under 42 U.S.C. § 405(g). 42 U.S.C. § 405(h). Section 405(g), in turn, states that judicial review may be obtained only after an individual receives a "final decision of the [Secretary] made after a hearing to which he was a party." *Id.* § 405(g).

As the Supreme Court has explained, this limited authorization of judicial review "contains two separate elements: first, a 'jurisdictional' requirement that claims be presented to the agency, and second, a 'waivable. . . requirement that the administrative remedies prescribed by the Secretary be exhausted.'" *Smith v. Berryhill*, 139 S. Ct. 1765, 1773 (2019) (alteration in original) (quoting *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)). A party, therefore, can only obtain judicial review of a claim that they are entitled to payment by Medicare by first presenting that claim to the agency in the context of the applicable administrative procedure governing specific payment requests. 42 U.S.C. §§ 405(h), 1395ii (incorporating Section 405(h) into the Medicare statute); *see also, e.g.*, *Weinberger v. Salfi*, 422 U.S. 749, 757, 762 (1975); *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984); *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000); *RICU LLC v. HHS*, 22 F.4th 1031, 1036 (D.C. Cir. 2022).

3. The Public Service Act's Regulation of Biological Products

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. 21 U.S.C. § 393(b).

FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act, 42 U.S.C. § 262. The Public Health Service Act's definition of a "biological product" includes any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product[] . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." *Id.* § 262(i). The FDA has broad authority to issue regulations to prevent the transmission of communicable diseases under Section 361 of the Public Service Health Act, as codified at 42 U.S.C. § 264(a).[1]

[1] The statute grants this authority to the Surgeon General, with the approval of the Secretary. The Office of Surgeon General was abolished by Section 3 of the Reorganization Plan No. 3 of 1966, *reprinted in* 80 Stat. 1610 (1966) (effective June 25, 1966), and all its functions were transferred to the Secretary of Health, Education, and Welfare (now the Department's Secretary)

Continued on next page.

In 1997, FDA proposed a new tiered, risk-based approach for regulating a rapidly growing category of biological products—human cells, tissues, and cellular or tissue-based products (HCT/Ps or HCT/P products). This approach was designed to provide only the degree of government oversight necessary to protect the public health, and it largely relies on manufacturers to accurately self-designate their products. *See* FDA, Dkt. No. 97N-0068, *Proposed Approach to Regulation of Cellular and Tissue-Based Products* (Feb. 28, 1997), http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM062601.pdf; *see also* Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,744 (May 14, 1998); Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting, 62 Fed. Reg. 9721 (Mar. 4, 1997).

Pursuant to its authority under Section 361 of the Public Health Service Act, FDA subsequently issued several regulations governing HCT/Ps. *See* Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001) (Final Registration

---

by Section 1 of the Reorganization Plan No. 3 of 1966, set out under 42 U.S.C. § 202. The Secretary's authority has been delegated to FDA. *See* FDA, *FDA Staff Manual Guides*, vol. II, SMG 1410.10.1.A.3 (Feb. 22, 2023), https://www.fda.gov/media/81983/download.

Rule); Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786 (May 25, 2004); Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement; Final Rule, 69 Fed. Reg. 68,612 (Nov. 24, 2004).

The regulations define HCT/Ps as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d). FDA determined that, in limited circumstances, certain HCT/Ps can be effectively regulated for FDA purposes solely by controlling the infectious disease risks that they present. Such products are regulated only under Section 361 of the Public Health Service Act and FDA's HCT/P regulations (21 C.F.R. Part 1271), even if they would otherwise meet the Public Health Service Act's definition of a "biological product." These products are sometimes referred to as "Section 361 HCT/Ps," after the communicable disease provision in Section 361 of the Public Health Service Act, 42 U.S.C. § 264. All other human and tissue-based products are regulated as drugs, devices, and/or biological drugs because they may present a greater degree of risk. 21 C.F.R. § 1271.20; Final Registration Rule, 66 Fed. Reg. at 5450. These products are sometimes referred to as "Section 351 HCT/Ps" and are subject to the Food,

Drug, and Cosmetic Act's adulteration, misbranding, and premarket approval requirements. *See* 21 U.S.C. §§ 321, 351, 352, 353; 21 C.F.R. § 1271.20; Final Registration Rule, 66 Fed. Reg. at 5449, 5456.

In order to fulfill its public health mission, FDA issues guidance related to its interpretation of the criteria governing HCT/Ps. *See, e.g.*, FDA, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use* (July 2020), https://www.fda.gov/media/109176/download. FDA also issues public statements warning of the potentially serious health risks of HCT/Ps, including public safety notifications informing the public of serious adverse event reports, consumer alerts, and other patient and consumer resources. As relevant here, FDA issued several public statements from 2019 to 2021 that addressed risks associated with consumers' use of certain HCT/Ps, including certain products marketed as regenerative medicine therapies. *See* FDA, *Public Safety Notification on Exosome Products* (Dec. 6. 2019), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products; FDA, *Consumer Alert on Regenerative Medicine Products Including Stem Cells and Exosomes* (July 22, 2020), https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/consumer-alert-regenerative-medicine-products-including-stem-cells-

and-exosomes; FDA, *Important Patient and Consumer Information About Regenerative Medicine Therapies* (June 3, 2021), https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies.

B. Factual Background

Concerned about the potential public health ramifications of HCT/Ps, CMS issued a technical direction letter on February 2, 2022, instructing Medicare contractors to deny claims for Medicare payment for certain processed amniotic and/or placental tissue intended to treat diseases and conditions. *See* JA 200-04. The letter stated that "[m]anipulated amniotic and/or placental tissue biologics for injections . . . have not been proven to be safe and effective" and referenced FDA's safety notices. JA 200. The letter was made effective as to services rendered on or after December 6, 2019. JA 201. On February 24, 2022, CMS issued a follow-up technical direction letter listing billing codes associated with particular HCT/P products that Medicare contractors could use to identify relevant products as part of an automated denial process. *See* JA 205-10.

On March 25, 2022, however, CMS issued a third technical direction letter rescinding the two February letters and providing guidance on how Medicare contractors should handle any claims that had already been

processed under the two prior letters. *See* JA 211-15. Specifically, the letter instructed Medicare contractors to remove system edits that automatically denied payment for amniotic and placental tissue product injections and to institute a claim-by-claim review process by medically knowledgeable individuals who would review each beneficiary's medical records to determine whether a claim was for reasonable and necessary services under 42 U.S.C. § 1395y(a)(1)(A), as well as any other applicable coverage and payment requirements. *See* JA 211. The letter also directed Medicare contractors to re-open any claims processed in accordance with the previous two letters and evaluate them under that same manual claim-by-claim review process. *Id.* Finally, the letter instructed Medicare contractors to remove all coverage articles and educational materials that were issued in response to the February letters. *Id.* The letter required that Medicare contractors comply within ten business days. JA 213.

C. Prior Proceedings

Plaintiff, Row 1 Inc., d/b/a Regenative, manufactures, markets, and distributes medical products containing HCT/Ps. As relevant to the current litigation, Regenative distributes two products, CoreText (now AmnioText) and ProText, which consist of Wharton's Jelly tissue—a connective tissue found in the umbilical cord. *See* JA 111, ¶ 13; Pl.'s Br. 5. Regenative alleges

that HHS, CMS, and Medicare contractors have improperly denied reimbursement for its products pursuant to CMS's technical direction letters to Medicare contractors regarding processing reimbursement for products containing HCT/Ps.

1. On March 15, 2022, Regenative filed a complaint in district court, alleging that HHS and CMS engaged in a "coordinated effort" with Medicare contractors to implement a "blanket denial of all claims for any amniotic or placental tissue products," "without notice-and-comment," JA 13, ¶ 7; JA 14, ¶ 8; JA 26, ¶ 78. In July 2022, after the February letters had been rescinded, Regenative filed an amended complaint incorporating allegations based on the technical direction letters. *See, e.g.*, JA 109-10, ¶¶ 10-11.

In the amended complaint, Regenative alleged that it has sold its products since 2020 and that Medicare generally covered those products until around the time of the February 2022 letters. JA 106, ¶¶ 4-5; *see also* JA 122-23, ¶ 84. *See* JA 109, ¶ 10. Regenative acknowledged that CMS has issued a third technical direction letter directing Medicare contractors to cease "automatically den[ying] payment for amniotic and placental tissue product injections and to institute claim-by-claim review to determine whether a claim meets the reasonable and necessary criteria." JA 109, ¶ 10. Regenative insisted, however, that this amounted to only a "faux-ceasing" of the prior policy and

that Medicare contractors continued to deny claims thereafter. *See* JA 129, ¶ 120; *see also* JA 110-11, ¶ 11; JA 126-29, ¶¶ 106-120.

In its amended complaint, Regenative claimed that the technical direction letters should have been issued through notice-and-comment, misunderstood distinctions between Section 351 and Section 361 HCT/P products, and intruded on FDA's statutory authority. *See, e.g.*, JA 108-09, ¶¶ 8-10; JA 111, ¶ 12; JA 122-26, ¶¶ 84-104. Regenative sought a preliminary injunction and an order that would, among other things, "[d]eclare[] that Regenative is a Section 361 product that does not require FDA approval and should be reimbursed as such" under Medicare "to maintain the status quo." JA 135, Prayer for Relief ¶ 1(a)(iii).

2. The government filed a motion to dismiss the complaint for lack of subject-matter jurisdiction, which the district court granted.

The court explained that Regenative's claim that the technical direction letters should have been issued through notice-and-comment rulemaking arose under the Medicare statute and therefore should have been presented to the agency, as required by 42 U.S.C. § 405(h). *See* JA 218-20. Relying on *Illinois Council*, 529 U.S. at 13-14, and *Ringer*, 466 U.S. at 614–15, the court rejected Regenative's contention that it brought procedural claims exempt from the requirements of Section 405(h). JA 219. The court also declined to embrace

Regenative's alternate argument that without review in this suit there would be "no review at all." JA 220-21 (quotation marks omitted). The court explained that affected beneficiaries and providers could seek review of denied Medicare claims and concluded that Regenative did not meet the "high bar" of showing that those "potential prox[ies were] 'highly unlikely' to pursue administrative review to challenge those requirements, thereby creating a '"practical roadblock" to judicial review.'" JA 221 (quoting *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 712 (D.C. Cir. 2011)). As the court explained, Regenative had not "pleaded or produced facts showing that there are no existing providers of its products that have pending claims before CMS," that providers would not have aligned incentives to bring such requests, or that Regenative could not act as an appointed representative on such claims. *Id.*

The district court also denied Regenative's request for mandamus, concluding that Regenative had not met its burden to show that the threshold requirements for jurisdiction over such claims was satisfied. First, the court explained that Regenative had not demonstrated that "the administrative appeals process is not an adequate remedy, which by itself bars mandamus jurisdiction." JA 222. Second, the court explained that mandamus relief was also unavailable on the independent threshold ground that "there is no clear,

ministerial duty" for CMS to take the actions Regenative requested. *Id.* (quotation marks omitted).

As a result of denying relief on other threshold grounds, the district court did not reach CMS's alternate argument that the suit could be dismissed as to all defendants on mootness grounds or its argument that the Medicare contractors could be dismissed for the additional reason that they are not the real parties in interest.

SUMMARY OF ARGUMENT

Regenative challenges two February 2022 technical direction letters in which CMS instructed Medicare contractors to automatically deny reimbursements for certain HCT/Ps, including two of Regenative's products. But those letters have been rescinded, and CMS has directed Medicare contractors to process claims for the relevant HCT/P products on a case-by-case basis and to reprocess any claims that were denied under the February letters. Contending that the now-rescinded letters should have been issued after notice and comment, Regenative asked the district court to declare that notice-and-comment rulemaking was required and that Regenative's products are eligible for Medicare coverage. Regenative also asked for relief in the form of mandamus directing the Secretary to engage in notice-and-comment rulemaking.

As the district court correctly concluded, this suit arises under Medicare: claims regarding Regenative's products must therefore be presented to the agency and any challenge to a reimbursement denial must be exhausted through the administrative process. And although the district court did not reach the issue, this suit is also moot: the challenged letters, and the policy they embodied, have been rescinded.

I. Under the Medicare statute, a plaintiff cannot obtain judicial review of claims "arising under" Medicare unless those claims have first been presented to the agency and administratively exhausted. *See* 42 U.S.C. §§ 405(g), (h); 1395ii. Here, Regenative argues that CMS was required to have proceeded by notice-and-comment rulemaking to change its reimbursement policy for Regenative's products, that the substantive policy was incorrect because its products are eligible for Medicare coverage, and that the Medicare contractors continue to improperly deny claims for reimbursement and ask for improper documentation in the process. These claims undoubtedly arise under the Medicare statute as, at bottom, they seek reimbursement for beneficiaries and providers who use Regenative's products.

Nor is there any merit to Regenative's contention that it is entitled to skip straight to judicial review because to hold otherwise would result in

"*complete* preclusion of judicial review." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 22-23 (2000). This Court's precedent makes clear that it is not enough for Regenative to assert that it cannot itself present claims for payment to the Secretary. *See, e.g.*, *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 711-12 (D.C. Cir. 2011); *RICU LLC v. HHS*, 22 F.4th 1031, 1038-39 (D.C. Cir. 2022). And Regenative has never explained why providers and beneficiaries would not share its interest in Medicare reimbursement for their use of Regenative's products. Nor, well over a year after the first CMS letter, has Regenative provided any support for its bare assertion that providers will stop purchasing and prescribing its products absent Medicare reimbursement such that no providers will exist to seek Medicare reimbursement. The district court thus correctly concluded that Regenative did not qualify for any exception to Medicare's channeling requirement.

II. Because Regenative failed to satisfy the threshold requirements for mandamus jurisdiction, the district court correctly dismissed Regenative's request for extraordinary relief under the Mandamus Act, 28 U.S.C. § 1361. Although it is not entirely clear, Regenative appears to ask this Court to compel the Secretary to engage in notice-and-comment rulemaking regarding HCT/P products, including its own. This claim for mandamus relief fails.

First, Regenative has not shown that it lacks an adequate remedy: as explained, the question of whether Regenative's products are eligible for reimbursement under Medicare can be decided through presentment of claims to the agency and, if necessary, subsequent administrative process.

Second, Regenative has not demonstrated that it has a clear right to relief or that CMS has a clear duty to act by proceeding with rulemaking. CMS has rescinded the original instructions it issued to Medicare contractors to automatically deny claims and has now instructed Medicare contractors to assess whether HCT/P products are reasonable and necessary for particular beneficiaries as part of claim-by-claim adjudications under 42 U.S.C. § 1395y(a)(1)(A). Regenative has pointed to no statutory provision imposing a mandatory duty requiring CMS to undertake notice-and-comment rulemaking establishing a universal reimbursement policy for HCT/P products, rather than proceeding by case-by-case adjudications under the general statutory standard that applies to all reimbursement claims.

III. Because the district correctly dismissed Regenative's suit for lack of subject-matter jurisdiction, it did not reach defendants' alternate arguments. If

this Court were to reach those arguments, however, it should direct the district court to dismiss this case as moot.

In March 2022, CMS rescinded the instructions to which Regenative objects. Any ruling as to Regenative's rights relative to those now-withdrawn instructions would thus be an advisory opinion. Nor do Regenative's baseless assertions that this rescission was fraudulent save its suit. Regenative alleges that one unnamed employee of one Medicare contractor informed an unidentified provider that the automatic policy was still being applied a few weeks after the recission. But even taking this as true, that conversation cannot bear the weight Regenative assigns to it: there is no evidence of a conspiracy between CMS and its Medicare contractors, let alone an ongoing one. And if claims are being erroneously denied, the proper remedy for addressing any such mistaken denials by a particular Medicare contractor is through the required administrative appeals process.

STANDARD OF REVIEW

This court reviews a dismissal for lack of subject-matter jurisdiction de novo. *RICU LLC v. HHS*, 22 F.4th 1031, 1035 (D.C. Cir. 2022). This court reviews the district court's determination that a plaintiff has failed to meet the threshold requirements for mandamus jurisdiction under 28 U.S.C. § 1361 de

novo and reviews the application of the equities for abuse of discretion. *American Hosp. Ass'n v. Burwell*, 812 F.3d 183, 190 (D.C. Cir. 2016).

ARGUMENT

I. The District Court Correctly Concluded that It Lacked Subject-Matter Jurisdiction Over Regenative's Claims for Declaratory and Injunctive Relief Because Regenative Did Not Present or Exhaust Its Claim Before the Secretary

The Medicare program is "a massive, complex" benefits program, and Congress took pains to ensure that CMS has the opportunity to correct any errors that occur in the administration of the program before the agency's determinations may be reviewed in court. *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 8, 13 (2000); *see also, e.g.*, *RICU LLC v. HHS*, 22 F.4th 1031, 1035-37 (D.C. Cir. 2022). To that end, the Medicare statute "channels most, if not all" challenges through the agency to "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts." *Illinois Council*, 529 U.S. at 8, 13. Federal court jurisdiction is available only over a "final decision" of the Secretary, after a claim has first been presented to the agency and administratively exhausted. 42 U.S.C. § 405(g); *see, e.g.*, *Illinois Council*, 529 U.S. at 13. The first of these requirements—that a claim first be "presented to the Secretary"—is "purely jurisdictional," and "cannot be waived by the Secretary." *Mathews v. Eldridge*, 424 U.S. 319, 328

(1976) (quotation marks omitted) (explaining that, "[a]bsent" presentment, "there can be no 'decision' of any type," "[a]nd some decision by the Secretary is clearly required by the statute"). Congress made this avenue of judicial review exclusive and foreclosed alternative bases for jurisdiction over any claim "arising under" Medicare. 42 U.S.C. § 405(h).

Regenative does not allege that its claims have ever been presented to the agency, let alone administratively exhausted. Instead, Regenative asserts that the channeling requirement does not apply because manufacturers like Regenative cannot "recover on any claim" for reimbursement under the Medicare statute. *See* Pl.'s Br. 11, 13-16. Regenative also contends that it advances a procedural claim that does not arise under the Medicare statute. *See* Pl.'s Br. 11, 16-20. Finally, Regenative argues that even if its claims are ones arising under Medicare, its claims qualify for a limited exception to the channeling requirement for cases in which application of Section 405(h) "would not simply channel review through the agency, but would mean no review at all," *Illinois Council*, 529 U.S. at 19. *See* Pl.'s Br. 12, 20-28. The district court correctly rejected these contentions.

A. Regenative's Claims Arise Under the Medicare Statute

1. The crux of Regenative's amended complaint is its allegation that CMS improperly instructed Medicare contractors to stop reimbursing

providers' claims for two of Regenative's products that contain HCT/Ps. Specifically, Regenative alleged that providers initially received reimbursement from Medicare contractors for Regenative's products but that Medicare contractors subsequently began "denying claims" for reimbursement. JA 106, ¶¶ 4-5. Regenative alleged that this was because CMS was engaged "in a coordinated effort" with Medicare contractors to create a blanket policy to automatically deny claims for reimbursement for two of Regenative's products. *See, e.g.*, JA 107-10, ¶¶ 7-8, 10-12. Part of this effort, according to Regenative, was the issuance of two technical direction letters in February 2022. JA 109, ¶ 10. Regenative further complained that these letters instructed Medicare contractors to "retroactively seek to recoup all payments made for these products," that the alleged policy denied reimbursement on the basis of a misclassification of Regenative's products, and that Medicare contractors were imposing improper documentary requirements. *See, e.g.*, JA 108-11, ¶¶ 8-12; JA 128, ¶ 117.

a. These claims undoubtedly arise under the Medicare statute. The Supreme Court has "construed the 'claim arising under' language quite broadly to include any claims in which 'both the standing and the substantive basis for the presentation' of the claims is the" Medicare statute, as well as any claims that are "'inextricably intertwined' with [a] claim for benefits" even if

they may also arise under another source of law. *See Heckler v. Ringer*, 466 U.S. 602, 611, 614-615 (1984) (first quoting 42 U.S.C. § 405(h); and then quoting *Weinberger v. Salfi*, 422 U.S. 749, 760-61 (1975)). As the district court recognized, the Supreme Court thus has made clear that "the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label." JA 219 (quoting *Ringer*, 466 U.S. at 615); *see also Illinois Council*, 529 U.S. at 13-14.

At bottom, Regenative seeks Medicare reimbursement for its products. Indeed, the basis for Regenative's Article III standing was its allegation that it was injured by CMS's actions because "many providers will not be able to purchase its products without reimbursement" from Medicare. *See* JA 111, ¶ 12; *see also* JA 132, ¶ 135. And Regenative asked the court to remedy that alleged injury by "[d]eclar[ing] that Regenative is a Section 361 product that does not require FDA approval and should be reimbursed as such to maintain the status quo." JA 135, Prayer for Relief ¶ 1(a)(iii).

b. Regenative's claim that CMS's now-rescinded instructions should have been issued by notice-and-comment rulemaking similarly arises under the Medicare statute. In *Ringer*, the Supreme Court held that a suit challenging payment methodology arose under the Medicare statute where the challenges

to the methodology were "inextricably intertwined" with claims for benefits and the relief requested included "a substantive declaration . . . that the expenses of [the] surgery are reimbursable under the Medicare Act." *Ringer*, 466 U.S. at 614 (quotation marks omitted). Here, too, the claim Regenative advances—that the policy required notice-and-comment rulemaking—is inextricably intertwined with Regenative's argument that its products are eligible for reimbursement under Medicare.

Regenative's contention that Medicare claims seeking coverage for its products were governed by an improperly promulgated policy goes hand-in-hand with its assertion that it suffered an injury—a decline in sales brought about by the denial of claims for its products—that can be remedied by a declaration that its products "should be reimbursed." *See, e.g.*, JA 111, ¶ 12; JA 135, Prayer for Relief ¶ 1(a)(iii). Regenative does not complain about the lack of notice and comment on principle; rather it seeks payment for providers who use its products (so that providers will buy more of Regenative's products), and its claim that notice-and-comment rulemaking was required turns on its contention that CMS changed a policy that permitted payment. *See, e.g.*, JA 135; JA 125, ¶¶ 96-100; JA 131-32, ¶¶ 133-134. Because the contention that the policy required notice-and-comment rulemaking relates directly to reimbursement policies under Medicare, the challenges clearly arise under the

Medicare statute whatever the label Regenative applies to them. *See, e.g.*, *Ringer*, 466 U.S. at 622.

2. Regenative's arguments to the contrary fail to advance its cause.

a. Regenative first insists that Section 405(h)'s requirement that "'[n]o action against the United States[] . . . shall be brought . . . to recover on any claim arising under this subchapter'" means that such channeling requirements are confined to "the individual processing of claims for monetary reimbursement for services or goods provided under the Medicare Act" and therefore do not apply to Regenative's claims because it is not "seeking any 'payment' under the Medicare Act." Pl.'s Br. 13-14 (first alteration in original) (quoting 42 U.S.C. § 405(h)).

This argument runs headlong into settled precedent. As the district court explained, the Supreme Court has expressly rejected "a distinction that limits the scope of § 405(h) to claims for monetary benefits." JA 219 (quoting *Illinois Council*, 529 U.S. at 14). And this Court has, for example, rejected a provider's argument that Medicare channeling did not apply to its "facial challenge" to a regulation that would impose "two cost limits" on reimbursements where the provider did not argue that either of the cost limits would change its current year's reimbursement. *Three Lower Ctys. Cmty. Health Servs., Inc. v. HHS*, 317 F. App'x 1, 2-4 (D.C. Cir. 2009) (per curiam).

Decisions from other courts of appeals likewise confirm that a plaintiff need not be directly seeking Medicare benefits to come within the scope of Medicare channeling. For example, the Third Circuit has explained that it was "irrelevant" for Medicare channeling purposes that the plaintiffs argued that they were seeking "reimbursement of alleged overpayments from a trust fund created as a result of a settlement with a tortfeasor" that had been made to CMS under the Secondary Payer statute, rather than review from a "benefit determination." *Fanning v. United States*, 346 F.3d 386, 401 & n.16 (3d Cir. 2003); *see also, e.g.*, *Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1112 & n.2 (9th Cir. 2003) (holding that the fact that the provider "seek[s] damages beyond the reimbursement payments available under Medicare does not exclude the possibility that their case arises under Medicare," where the provider was simultaneously pursuing a claim for reimbursement for Medicare payments).

Regenative's argument that its suit does not arise under Medicare because it "could not seek[] reimbursement or benefits" on its own behalf, *see* Pl.'s Br. 16, cannot be squared with this Court's analysis in *RICU*. In *RICU*, the fact that RICU could not "bring an administrative challenge directly because it [wa]s not a Medicare enrolled provider" and did not seek "resolution of a specific claim for reimbursement" was no barrier to this Court's holding that RICU's claim arose under the Medicare statute and that

RICU had failed to present a claim as required under Section 405(h). *See RICU*, 22 F.4th at 1035-39. Likewise, in *Council for Urological Interests*, this Court considered a "whole category of affected parties" that "has no way to obtain review through Medicare Act channels" but did not hold that such parties are exempted from channeling because their claims did not arise under Medicare. *See Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708-11 (D.C. Cir. 2011).

That the plaintiffs in *Illinois Council* and *Ringer* happened to include beneficiaries or providers who could bring claims for reimbursement does not advance Regenative's argument. *See* Pl.'s Br. 15-16. The Supreme Court nowhere indicated that the identities of the plaintiffs had any bearing on the bedrock principle established in those cases that the broad sweep of the Medicare statute's channeling provision is intended to "assure[] 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." *Illinois Council*, 529 U.S. at 2.

The practical upshot of Regenative's strained reading of Section 405(h) should not be ignored. Regenative acknowledges that Congress required Medicare beneficiaries (and providers who treat them) to go through the

administrative process before they may challenge any action related to the reimbursement of benefits. Yet, under Regenative's theory, third-party manufacturers that are not beneficiaries may leapfrog this requirement and head straight to federal court—and do so even where beneficiaries or providers share an interest in challenging that same action in the context of a concrete claim for reimbursement. This proposal cannot be sustained without undermining the core purpose of Medicare channeling.

b. Regenative's attempt to carve out its procedural claim is equally without merit. The two cases from this Court on which Regenative relies for the proposition that procedural challenges are exempt from channeling have been superseded by subsequent Supreme Court precedent. *See* Pl.'s Br. 16-18 (first citing *National Ass'n of Home Health Agencies v. Schweiker*, 690 F.2d 932 (D.C. Cir. 1982); and then citing *Humana of S.C., Inc. v. Califano*, 590 F.2d 1070 (D.C. Cir. 1978)). In *Ringer*, the Supreme Court emphasized that "to be true to the language of the statute, the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label." *Ringer*, 466 U.S. at 615. And, in *Illinois Council*, the Supreme Court reiterated that Section 405(h) does not recognize distinctions based on the "'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus

the 'fact-specific' nature of the challenge, the 'collateral' versus 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought," or "a distinction that limits the scope of § 405(h) to claims for monetary benefits." *Illinois Council*, 529 U.S. at 13-14. Recognizing that "the channeling requirement does not vary based on how a claim is characterized," the district court correctly concluded that it lacked subject-matter jurisdiction over Regenative's procedural claim. *See* JA 219.

Relatedly, Regenative cannot circumvent Medicare's channeling requirements by asserting that its procedural claim under the Administrative Procedure Act (APA) "is separate and apart from the procedural requirements under the Medicare Act and gives separate and independent standing and a substantive basis for Regenative's causes of action." *See* Pl.'s Br. 19. Regenative did not attempt to make such distinctions between the statutory sources of its procedural claims and therefore has forfeited such arguments. *See* Dkt. No. 25, at 12-13 (Plaintiff's Opposition to Motion to Dismiss) (arguing that Section 405(h) "leaves open other actions under the Medicare statute, such as here, to hold the Department accountable to follow required formal rulemaking procedures under Sections 405(a) and 1395hh, as well as the APA"). *See, e.g.*, *Durant v. District of Columbia Gov't*, 875 F.3d 685, 695 (D.C.

Cir. 2017) (explaining that an "argument comes too late" when raised for the first time on appeal).

In any event, the Supreme Court and this Court have held that Medicare channeling applies to claims that could also be described by a creative litigant as arising under the APA or the Constitution, and not the Medicare statute. *See Ringer*, 466 U.S. at 622; *see also Three Lower Ctys. Cmty Health Servs., Inc.*, 317 F. App'x at 2 ("Parties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge."). Indeed, the allegations here underscore why no such distinction should be made. Regenative does not complain about the lack of notice-and-comment rulemaking in a vacuum: Regenative contends that CMS was required to provide notice and comment because CMS allegedly altered the reimbursement policy for Regenative's products, thereby causing harm to Regenative by the loss of business from providers who cannot receive reimbursement. *See supra* pp. 13-14; *see also Ringer*, 466 U.S. at 614.

Nor does Regenative offer any limiting principle for its theory that Section 405(h) allows suits to "vindicate an interest in procedural regularity." Pl.'s Br. 16 (quoting *National Ass'n of Home Health Agencies*, 690 F.2d at 937). Regenative does not provide any textual basis for distinguishing its current

challenge from, for example, a claim that CMS acted arbitrarily and capriciously in responding to comments in the course of rulemaking. Yet, the Supreme Court has rejected such attempts to circumvent Section 405(h)'s jurisdictional presentment requirement in *Ringer* and *Illinois Council*. *See supra* pp. 29-30.

c. Finally, Regenative's argument that its claim does not arise under Medicare because it has standing based on an alleged reputational injury fares no better. This argument hinges on certain language in the February letters that Regenative asserts suggested that certain HCT/P products, including Regenative's, might not be regulated as a Section 361 HCT/P products and instead might be regulated as drugs, devices, and/or biological drugs subject to the provisions of the Food, Drug, and Cosmetic Act and the Public Health Service Act, including the Food, Drug, and Cosmetic Act's adulteration, misbranding, and premarket approval requirements. Regenative contends that this language "resulted in Regenative's products being perceived as marketed and promoted illegally" and without "proper regulatory clearance." *See* Pl.'s Br. 20, 26. But CMS's technical directive letters were based on whether HCT/P products (including Regenative's) were "safe and effective" and did not single out Regenative's products as illegally marketed, *see* JA 200-10. CMS, moreover, rescinded the February letters shortly after their issuance.

In any event, even assuming arguendo that Regenative has sufficiently pled a concrete, non-speculative reputational injury arising from the February letters, Regenative has not cited any relevant case (and we are not aware of any) holding that an alleged reputational injury connected to Medicare reimbursement takes a suit outside Medicare.[2] Nor does Regenative grapple with the limits of its theory. Indeed if it were enough to claim that reputational damage was caused by the denial of reimbursement for a product—including because the product was, for example, not deemed to be safe and effective with respect to a type of treatment—it is hard to see why suppliers, manufacturers, and providers would not be able to frequently bypass Section 405's channeling requirements by claiming that they, too, have suffered reputational injury through denial of Medicare coverage.

[2] The two district court cases on which Regenative relies do not advance its argument. *See* Pl.'s Br. 19 (first citing *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 112-13 (D.D.C. 2009); and then citing *Akebia Therapeutics, Inc. v. Becerra*, 548 F. Supp. 3d 274, 276 (D. Mass. 2021)). *Baxter*'s discussion of standing related to a question of whether a manufacturer was within the zone of interests of the Medicare statute and thus does not address whether the basis for such standing arises under that statute. *Baxter*, 643 F. Supp. 2d at 114. *Akebia*'s discussion of standing was confined to its description of the plaintiff's argument that "only Medicare beneficiaries—not drug manufacturers—have standing to bring administrative appeals to the Medicare Appeals Council" and therefore has no bearing on the question of whether that plaintiff's Article III standing in district court arose under the Medicare statute. *Akebia*, 548 F. Supp. 3d at 279 (quoting *Akebia Therapeutics, Inc. v. Azar*, 976 F.3d 86, 91 (1st Cir. 2020)).

B. No Exception to the Channeling Requirement Applies

As demonstrated, Regenative's suit arises under the Medicare statute; the statute's channeling requirements therefore apply. Rather than allege it has met those requirements, Regenative asserts that its claims may proceed because otherwise there would be no review at all. As the district court correctly held in dismissing the suit for lack of subject-matter jurisdiction, that argument is without merit.

1. In *Illinois Council*, the Supreme Court discussed one limited exception to the channeling requirement where "application" of Section 405(h) "would not simply channel review through the agency, but would mean no review at all." *Illinois Council*, 529 U.S. at 19. The Court emphasized that a plaintiff could not avoid the channeling requirement merely because channeling might result in "added inconvenience or cost in an isolated, particular case." *Id.* at 22. "Rather, the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." *Id.* at 22-23; *see also American Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005) (holding that the exception applies only "when roadblocks practically cut off *any* avenue to federal court" (emphasis added)).

This Court "start[s] from the premise that" the no-review exception "is not intended" to allow for jurisdiction "in every case where section 405(h) would prevent a particular . . . entity from seeking judicial review" and therefore has understood the no-review exception as limited to those circumstances "where the only entities able to invoke Medicare Act review are *highly unlikely* to do so," such that "their unwillingness to pursue a Medicare Act claim poses a serious 'practical roadblock' to judicial review." *Council for Urological Interests*, 668 F.3d at 711, 712 (emphasis added). In *RICU*, for example, this Court explained that although the plaintiff telehealth medicine company could not "bring an administrative challenge directly because it is not a Medicare enrolled provider," the no-review exception did not apply because plaintiff's "client hospitals are adequate proxies to channel RICU LLC's general claim that its services are eligible for Medicare reimbursement through a concrete claim for payment." *RICU*, 22 F.4th at 1038-39; *see also American Chiropractic Ass'n*, 431 F.3d at 816-17 (holding that an association had adequate proxies because some of its members could obtain administrative review by providing services to Medicare enrollees, who could then submit specific claims for reimbursement).

The default rule thus is that a provider's or beneficiary's interest in reimbursement for a manufacturer's product or a supplier's services is

ordinarily sufficient to defeat a claim that channeling requirements may be ignored. The result is that manufacturers and suppliers will generally not be able to demonstrate that they qualify for the no-review exception to channeling.

The other courts of appeals to have addressed this issue are in accord. For example, the Fifth Circuit has held that Section 405(h) barred a premature suit where the plaintiff athletic trainers could not bring administrative claims directly because the physicians who used the plaintiffs' services could "pursue administrative review" and had "sufficient incentive to challenge the rule." *National Athletic Trainers Ass'n v. HHS*, 455 F.3d 500, 504, 507-08 (5th Cir. 2006). And the Ninth Circuit reached a similar conclusion in *Sensory Neurostimulation, Inc.*, explaining that although a medical device supplier could not itself administratively challenge the agency's decision whether to cover its product under Medicare, no exception to channeling applied because "an administrative channel for review exist[ed]" for other aggrieved parties (such as beneficiaries) to bring such a claim. *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 983-84 (9th Cir. 2020).

Regenative has not shown that providers and beneficiaries are "highly unlikely" to pursue administrative review, thereby creating a "'practical roadblock' to judicial review," as required under this Court's precedent. *See*

Council for Urological Interests, 668 F.3d at 712; JA 220-21. Just as in *RICU*, the providers and beneficiaries that have used Regenative's products have the same general interests as Regenative, *i.e.*, Medicare reimbursement for use of Regenative's products. And to the extent that Regenative argues that it would be illogical for providers to continue using its products, it has offered no information about, for example, competitor products to which the providers would be likely to turn, particularly as those competitor products presumably also would involve HCT/Ps and would thus be subject to the same issues Regenative alleges apply to its products.

Regenative never argues that no providers or beneficiaries could bring administrative claims. To the contrary, Regenative's allegations indicate that there are providers who have successfully submitted claims for reimbursement beginning in February 2020, *see* JA 106, ¶ 4, which would have been subject to reopening and automatic denial under the February 2022 letters, *see* JA 201 (instructing Medicare contractors to "re-open and adjust any paid claims" after "December 6, 2019"). Thus, the record suggests the existence of a pool of providers who previously submitted reimbursement requests for Regenative's products and could therefore act as proxies for Regenative. And Regenative's amended complaint likewise indicates that there is at least one provider who was sufficiently interested in reimbursement to contact Medicare contractors in

"mid-April" 2022. *Cf.* JA 127, ¶ 108. Indeed, more than a year after first alleging that CMS's actions "will create imminent harm to Regenative, as it may soon need to close its business because many providers will not be able to purchase its products without reimbursement, *see* JA 15, ¶ 10, Regenative has not represented to this Court that providers and beneficiaries have, in fact, entirely stopped purchasing its product, such that there is no set of providers who can challenge any erroneous denials of Medicare reimbursement.

2. Regenative's attempt to distinguish this Court's binding precedent is unpersuasive.

a. Regenative's attempts to rely on *Council for Urological Interests* as significantly expanding *Illinois Council*'s narrow exception to Medicare channeling fails. *See* Pl.'s Br. 25-26. As discussed, in *Illinois Council* the Supreme Court emphasized that Section 405(h) "demands the 'channeling' of virtually all legal attacks through the agency." *Illinois Council*, 529 U.S. at 13. The Supreme Court thus explained that a party can only establish an exception to that channeling requirement in the extraordinarily limited circumstance where, as a "general" matter, the "hardship" in bringing an administrative claim would result in the "*complete* preclusion of judicial review" of the challenge to agency action. *Id.* at 22-23.

In *Council for Urological Interests*, this Court interpreted this complete preclusion requirement to apply because the "unique characteristics of the hospitals' relationship to the Council" meant that the hospitals' own interests were furthered by the very reimbursement policy that the plaintiff wanted to challenge. *See Council for Urological Interests*, 668 F.3d at 713. And those "unique" circumstances were demonstrated through detailed allegations that the challenged regulation conferred specific benefits to the hospitals that were contrary to the interests of the Council's members, such as allowing the "hospitals to reassert control over the procurement" of certain equipment and "to purchase expensive laser equipment from urologist joint ventures at fire sale prices." *Id.* (quotation marks omitted). Moreover, as the Court explained, "history confirms the Council's contentions" because three years had elapsed since the implementation of the rule without a single administrative challenge to the regulation. *Id.*

In *RICU*, this Court clarified that the unique circumstances identified in *Council for Urological Interests* were to be found sparingly. *RICU*, 22 F.4th at 1038-39. The Court therefore affirmed that manufactures or suppliers will ordinarily *not* be able to qualify for an exception when challenging reimbursement denial policies for their products or services because the

providers and beneficiaries who use them will generally be motivated to raise those arguments in the course of concrete claims for reimbursement. *Id.*

In stark contrast to the Council for Urological Interests' detailed allegations about why hospitals benefitted from the interpretation with which the Council took issue and therefore were unlikely to challenge it themselves, Regenative has offered no explanation for why providers' interests would be inherently averse to Regenative's. As described *supra* pp. 36-38, Regenative fails to provide any specific allegations to support its conclusory assertion that no adequate proxy will exist because providers will stop using its products and therefore will not seek reimbursement. *Cf. Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). Regenative's reliance on *Council for Urological Interests* is thus entirely misplaced and accepting Regenative's capacious theory would expand significantly *Illinois Council*'s narrow exception.

b. For the first time on appeal, Regenative also argues that—so long as it has broadly alleged that there are no adequate proxies to press its claim for reimbursement—the government bears an affirmative burden to prove that there *are* such entities willing to bring the exact claims Regenative raises. *See* Pl.'s Br. 12, 24-27. As an initial matter, Regenative has waived this argument by failing to raise it below. *See* Dkt. No. 25, at 16-18 (arguing instead that there was no adequate proxy because providers would have no incentive to

"purchase purportedly unlawful products and then bring an administrative claim to the federal government for reimbursement" and because Medicare contractors were allegedly requiring "providers to submit impossible-to-obtain documentation for such claims"); *see, e.g.*, *Durant*, 875 F.3d at 695.

Even taken on its own terms, that new argument has no merit. Contrary to Regenative's contentions, *see* Pl.'s Br. 23, 25-27, this Court has never required the government to produce evidence (through affidavits or otherwise) that a provider or beneficiary is currently raising the same claims as the plaintiff. As discussed, settled precedent proceeds from precisely the opposite premise that the exception described in *Illinois Council* "is not intended" to allow for jurisdiction "in every case where section 405(h) would prevent a particular . . . entity from seeking judicial review." *Compare Council for Urological Interests*, 668 F.3d at 711-12, *and RICU*, 22 F.4th at 1038-39, *with* Pl.'s Br. 23, 25-27.

Regenative strays even farther from this Court's analysis by urging that dismissal would only be appropriate if CMS produced evidence that a provider or beneficiary is likely to raise every individual claim or cause of action in Regenative's complaint. *See* Pl.'s Br. 23-24, 26. That is not how this Court has analyzed the availability of adequate proxies. In *RICU*, for example, this Court examined whether the supplier's client-hospitals were generally interested in

receiving reimbursement from RICU and therefore would be likely to challenge the relevant regulation foreclosing reimbursement. *RICU*, 22 F.4th at 1038-39. This Court did not consider whether the client-hospitals would raise every single argument that RICU had asserted in its complaint. *Id.* Nor can any per se rule be gleaned from *Council for Urological Interests*. Although this Court noted that HHS did not point to any contrary indications that hospitals had an incentive to bring such challenges, such as (but not limited to) by providing affidavits in that case in light of the unique circumstances presented in that case, *Council for Urological Interests*, 668 F.3d at 713, this does not mean as Regenative suggests, *see* Pl.'s Br. 25-26, that courts must always accept a plaintiff's assertion that no adequate proxy exists.

Nor does the isolated quotation from *Council for Urological Interests* that Regenative excerpts suggest that the inquiry requires identification of an entity who "is pursuing or is willing to pursue the . . . 'particular claim[s]'" the plaintiff wishes to pursue. *See* Pl.'s Br. 26 (second alteration in original) (quoting *Council for Urological Interests*, 668 F.3d at 713). Read in the context of the entire opinion, this Court had already defined "a particular claim" as the overarching "challenge to the 2008 regulations" and not as referencing particular arguments that might be advanced. *See Council for Urological Interests*, 668 F.3d at 708, 713-14.

In any event, Regenative has never adequately explained why providers seeking reimbursement would not have incentives to raise the types of arguments that Regenative raises here. As discussed, Regenative alleges that the policy requiring denials was arbitrary and capricious, that CMS exceeded its statutory authority in reclassifying Regenative's products, that the denial could not go forward before the requisite rulemaking procedures were not followed when the policy was adopted, and that Medicare contractors were asking for inappropriate forms of documentation as a condition of reimbursement. *See* Pl.'s Br. 22-24. These are all roadblocks to payments that providers and beneficiaries would wish to overcome. Indeed, the real-world evidence belies Regenative's assertion: a recent district court complaint filed by providers who presented claims for reimbursement for HCT/P products allegedly covered by the policy challenged here raised the same kinds of arguments as Regenative. *See* Complaint at 50-54, 57, *Greiner Orthopedics, LLC v. Becerra*, No. 1:23-cv-01047 (D.D.C. Apr. 14, 2023) (seeking declaratory and injunctive relief under the Medicare statute's procedural requirements and the APA's arbitrary and capricious standard, among other things); *cf. Coalition for Underground Expansion v. Mineta,* 333 F.3d 193, 198 (D.C. Cir. 2003) (noting that courts may consider materials outside the pleadings in ruling on a 12(b)(1) motion to dismiss for lack of subject-matter jurisdiction).

c. Regenative's invocation of the "possible implications of the Anti-Kickback Statute" is a red herring. *See* Pl.'s Br. 22-23. There is no requirement that Regenative become a provider's or beneficiary's assignee for providers or beneficiaries to be adequate proxies. Rather, the question is simply whether Regenative has shown that it is "highly unlikely" that there are providers or beneficiaries who wish to seek reimbursement for its products. *See Council for Urological Interests*, 668 F.3d at 712. And, for the reasons described *supra* pp. 36-38, Regenative has not done so here.

Moreover, neither Regenative nor the district court case on which it relies identifies the conduct that would be undertaken as part of the assignment of an administrative claim that would give rise to the anti-kickback concern, *see* Pl.'s Br. 23 (citing *Akebia Therapeutics, Inc. v. Becerra*, 548 F. Supp. 3d 274, 286 n.15 (D. Mass. 2021)), as would be necessary to evaluate whether the conduct would constitute a "knowing[] and willful[]" attempt at a "kickback," *see* 42 U.S.C. § 1320a-7b(b)(2); *see also* 42 C.F.R. pt. 1008 (providing for a process by which Regenative could seek a binding advisory opinion on the basis of all relevant facts as to its proposed conduct in seeking assignment).

II. Regenative Has Not Made the Extraordinary Showing Needed to Demonstrate Entitlement to Mandamus Relief

The district court also correctly dismissed Regenative's claim for relief under the Mandamus Act, 28 U.S.C. § 1361, because Regenative failed to

satisfy the threshold requirements for mandamus. JA 222. Mandamus is a "drastic" remedy reserved for "extraordinary situations." *Kerr v. U.S. Dist. Court for the N. Dist. of Cal.*, 426 U.S. 394, 402 (1976); *see also, e.g.*, *13th Reg'l Corp. v. U.S. Dep't of Interior,* 654 F.2d 758, 760 (D.C. Cir. 1980) (explaining that "because of the potential conflict between the branches of government engendered by use of this remedy, [courts] have limited its application to only the clearest and most compelling cases") (alteration omitted) (quotation marks omitted).

To establish mandamus jurisdiction, Regenative bears the burden of establishing "a clear and indisputable right to relief." *In re Cheney*, 406 F.3d 723, 729 (D.C. Cir. 2005) (en banc) (quotation marks omitted). Regenative must first show that it has satisfied the three threshold criteria that: "(1) [it] 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 plaintiff." *Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir. 2002) (quoting *Northern States Power Co. v. U.S. Dep't of Energy*, 128 F.3d 754, 758 (D.C. Cir. 1997)). And, even if all jurisdictional requirements are met, "a court may grant relief only when it finds compelling equitable grounds." *American Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (quotation marks omitted). Regenative has not met any part of this substantial burden.

A.1. First, as the district court emphasized, Regenative "has not shown that the administrative appeals process is not an adequate remedy, which by itself bars mandamus jurisdiction." JA 222 (citing *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 810 (D.C. Cir. 2001) ("[W]e must first examine all other possible avenues of relief to ensure that the hospitals have fully exhausted those which were available."); and *id.* at 813 (stating that mandamus is available only when the claimant has exhausted administrative remedies)).

For the reasons described, *supra* pp. 22-33, Regenative's claim arises under the Medicare statute, which has a review scheme requiring channeling. Under the scheme set up by Congress, manufacturers like Regenative can generally rely on providers and beneficiaries to seek reimbursement and therefore have an alternative remedy through adequate proxies who can raise the same arguments in the context of concrete claims for reimbursement that would be subject to judicial review. *Compare* Pl.'s Br. 30, 33, *with supra* pp. 34-44. Regenative cannot show, therefore, that it is entitled to the extraordinary remedy of mandamus relief. *Cf. Heckler*, 466 U.S. at 617 (holding that mandamus relief is not available where there is an adequate alternative remedy available through Medicare channeling).

2. Although this Court has contemplated mandamus relief with respect to certain procedural challenges brought by Medicare providers, those cases do not assist Regenative. *See* Pl.'s Br. 28-30, 33. This Court has, for example, concluded that mandamus relief might be available to address a procedural claim that HHS was not processing administrative appeals within the statutorily mandated time period. The Court has explained that the plaintiffs' injuries could not be remedied by escalation of individual cases given the "systemic" nature of the delays (subject to equitable considerations). *See American Hosp. Ass'n*, 812 F.3d at 189-93, *cited at* Pl.'s Br. 28-30. But addressing that sort of request for claims-processing procedural relief is not inextricably intertwined with the merits of any substantive reimbursement policy raised in any pending claim. Even if a provider were to succeed, for example, in demonstrating unreasonable delay, relief would be processing of the provider's claim, which could result in either payment or not.

And in two other cases from this Court, cited by Regenative for different points, this Court likewise isolated a claims-processing procedural claim—whether intermediaries had to reopen hospitals' reimbursement claims pursuant to a regulation that required automatic reopening of reimbursement decisions whenever HHS issued a notice of inconsistency—from the substantive merits of the reimbursement claims. *See Monmouth*, 257 F.3d at

813, *cited at* Pl.'s Br. 28; *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10-11 (D.C. Cir. 2005) (extending *Monmouth* to other hospitals based on the same notice of inconsistency, *cited at* Pl.'s Br. 33. Moreover, in doing so, this Court concluded that those particular plaintiffs had no alternate avenue of relief that could be properly channeled. *Monmouth*, 257 F.3d at 813, 815.

The reasoning of these cases does not extend here: as explained, Regenative's claim arises under the Medicare statute and whether Regenative's products are covered by Medicare can be directly resolved in a challenge to a claim denial. *See supra* p. 22-44. The result Regenative ultimately seeks is not compliance with a procedural requirement, but rather reimbursement under Medicare for the products it sells.

B. Regenative also cannot satisfy the independent threshold requirements that it "has a clear right to relief" and "the defendant has a clear duty to act." *See, e.g.*, *Power*, 292 F.3d at 784 (quotation marks omitted).

In its district court briefing, Regenative claimed that notice-and-comment rulemaking was required because CMS's technical direction letters "covertly adopted a new Policy that changed the substantive legal standard regarding the scope of benefits available to Medicare and Medicaid beneficiaries and the payment for services, and, in so doing, explicitly identified . . . Regenative's products as one for which all claims should be

automatically denied." Dkt. No. 25, at 19. Although CMS issued a third technical direction letter rescinding the original letters and instructing Medicare contractors to instead evaluate such claims on a case-by-case basis to determine whether they satisfy the reasonable and necessary criteria outlined under 42 U.S.C. § 1395y(a)(1)(A), *see supra* pp. 11-12, Regenative insists that it is entitled to mandamus relief ordering CMS to undertake notice-and-comment rulemaking because it believes that the February 2022 policy is still being implemented in individual reimbursement decisions. *See* Pl.'s Br. 9, 33-34.

But that is not the type of claim that establishes a clear right to mandamus relief. Regenative cannot show that CMS has failed to abide by a "clear, ministerial duty to act" to address reimbursement for HCT/P products like the ones Regenative sells by rulemaking. *See* JA 222 (quotation marks omitted); Pl.'s Br. 29-30 (arguing that the Court should order CMS to "promulgate regulations following the required notice-and-comment procedure.").

Regenative's claim for relief is further doomed by CMS's March letter. Even assuming arguendo that the February letters were invalid because they did not undergo notice-and-comment rulemaking, CMS has rescinded those letters and instructed Medicare contractors to make their coverage and payment determinations of HCT/P products (including by reopening any

denials previously issued pursuant to the withdrawn February letters) based on whether these items meet the "reasonable and necessary" statutory requirement. *See supra* pp. 11-12. Regenative cannot insist on across-the-board approval of reimbursement claims under this standard: the currently applicable instruction mirrors the longstanding statutory standard that governs all reimbursement decisions and is the antithesis of a ministerial duty. It requires the agency and its Medicare contractors to employ expertise to determine whether a myriad of products and services meet the statutory reasonable and necessary standard for treating each beneficiary's specific medical condition.

Nor is there any basis for Regenative's claim that CMS has a clear and indisputable duty to promulgate regulations governing payment for HCT/P products. Regenative does not identify any legal authority that requires CMS to promulgate any additional regulations addressing this particular type of product's eligibility for payment, and, as explained, CMS and Medicare contractors take a variety of approaches with respect to decision-making, including on a case-by-case basis. *See supra* pp. 4-5. Indeed, the Medicare statute unequivocally instructs that "no payment may be made" for any claim that does not pass muster under the reasonable and necessary standard; it does not direct notice-and-comment rulemaking to direct particular coverage determinations in favor of particular suppliers. 42 U.S.C. § 1395y(a)(1)(A).

Regenative's contention that a "shadow rule[]" exists, *compare* Pl.'s Br. 33, *with infra* pp. 54-58, does not change this analysis. As an initial matter, such a "shadow rule" is difficult to square with the March letter, which rescinded the earlier letters and directed a return to case-by-case adjudication, even for claims that had already been processed under the February letters. But more fundamentally, as explained, there is no statutory provision requiring CMS to promulgate regulations that specifically address reimbursement for HCT/P products, rather than on the case-by-case evaluation of whether such products are reasonable and necessary in individual claims for reimbursement. And CMS may correct any erroneous denials, including any that rely on the rescinded letters, on administrative appeal. That is the proper procedure for addressing any "shadow rule."

C. Although not addressed by the district court, Regenative has also not shown that the equitable case for mandamus relief clearly weighs in its favor. *See* Pl.'s Br. 33-34. The "equitable grounds" for mandamus must be "clear and compelling" for this extraordinary writ to issue. *13th Reg'l Corp.*, 654 F.2d at 760. As this Court has recognized, "[p]erhaps counseling most heavily against mandamus is the writ's extraordinary and intrusive nature, which risks infringing on the authority and discretion of the executive branch." *American Hosp. Ass'n*, 812 F.3d at 192.

Here, given that the challenged policy is no longer extant, there can be no countervailing benefit that could possibly justify intruding on CMS's reimbursement authority. *See* 55 C.J.S. *Mandamus* § 15 (May 2023 Update) (explaining that "courts generally will not issue a writ of mandate to enforce an abstract right that are of no practical benefit to the petitioner"); *cf. United States v. Sanchez-Gomez*, 138 S. Ct. 1532, 1540 (2018) (explaining that supervisory mandamus cases are subject to the "normal mootness rules").

As explained, CMS issued a third technical direction letter "rescinding" its earlier instructions to automatically deny reimbursement for HCT/P products, including Regenative's. JA 211; *see supra* pp. 11-12 . If beneficiaries or providers who receive a denial believe that a Medicare contractor has acted contrary to these instructions, the remedy is to raise that argument as part of the appeals process from that denial. Equity does not support permitting Regenative to skip the line to seek a court order that CMS undertake notice-and-comment rulemaking.

III. Regenative's Suit Is Moot Because CMS Has Already Rescinded the Challenged Instructions

The district court did not reach defendants' alternate arguments because it correctly dismissed Regenative's suit for lack of subject-matter jurisdiction based on a failure to present the claim to the agency and failure to show entitlement to mandamus. But were this Court to reach such arguments,

dismissal as to all defendants is required for the additional reason that Regenative's suit is moot.[3]

A. This Court has long recognized that prospective relief such as "declaratory and injunctive relief would no longer be appropriate" if intervening events have provided the relief sought by the plaintiff against the defendant. *National Black Police Ass'n v. District of Columbia*, 108 F.3d 346, 349-50 (D.C. Cir. 1997); *see also, e.g.*, *Princeton Univ. v. Schmid*, 455 U.S. 100, 102-03 (1982) (per curiam) (declining to "decide hypothetical issues or to give advisory opinions" as to the validity of Princeton's prior rule where Princeton had rescinded the rule while litigation was pending). Where, as here, the intervening events occurred during the pendency of litigation, courts generally will conclude that the subsequent action has rendered the case moot when: "'(1) there is no reasonable expectation that the alleged violation will recur, and (2) interim relief or events have completely or irrevocably eradicated the

[3] Although the district court correctly dismissed the suit as to all defendants, were this Court to remand defendants reserve all other defenses not reached by the district court, including that defendant Medicare contractors should be dismissed from the suit because they are not the real parties in interest as agents of the government as expressly noted in the regulations and recognized by numerous courts, including this one. *See* 42 C.F.R. § 421.5(b); *see also, e.g.*, *Pine View Gardens, Inc. v. Mutual of Omaha Ins. Co.*, 485 F.2d 1073,1074-75 (D.C. Cir. 1973) (finding diversity jurisdiction unavailable in suit against Medicare contractor for unpaid benefits because "[t]he [Medicare statute] and regulations[] . . . make it clear that [the contractor] is an agent for the Government").

effects of the alleged violation.'" *American Freedom Def. Initiative v. Washington Metro. Transit Auth.*, 901 F.3d 356, 362 (D.C. Cir. 2018) (quoting *National Black Police Ass'n*, 108 F.3d at 349).

In *Friends of Animals v. Bernhardt*, for example, this Court explained that "the government's abandonment of a challenged regulation is just the sort of development that can moot an issue." *Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1203 (D.C. Cir. 2020). In that case, the agency had withdrawn the challenged findings about sport-hunted animal "trophies" after this Court struck down similar findings from other years for lack of notice and comment. *Id.* at 1201-02. Even though the agency announced that it would use the same information on which the original findings were made when proceeding through informal adjudications, this Court held that it could "do nothing to affect appellants' rights relative to those now-withdrawn findings" and therefore appellants' claims were "'classically moot.'" *Id.* at 1203 (quoting *Akiachak Native Cmty. v. U.S. Dep't of Interior*, 827 F.3d 100, 106 (D.C. Cir. 2016)).

So too here with the now-withdrawn technical direction letters that Regenative challenges. Regenative seeks declaratory and injunctive relief to prevent application of instructions in two CMS letters from February 2022 to Medicare contractors to automatically deny reimbursement for HCT/Ps,

including Regenative's products. *See supra* pp. 13-14, 22-25. But CMS "rescind[ed]" those earlier letters on March 25, 2022. JA 211. That letter instructed Medicare contractors to: (1) "institute claim-by-claim review to determine whether a claim [for such products] meets the reasonable and necessary criteria" required by statute; (2) to "re-open[]" claims that may have been denied pursuant to the first two letters and to "evaluate[]" them under "the same claim-by-claim review"; and (3) to "delete all related coverage articles and educational materials that were issued in response to" the first two letters. *Id.*

As in *National Black Police Ass'n* and *Friends of Animals*, a decision on the merits of the allegations regarding the original letters would be an advisory opinion because there is nothing left to do with respect to Regenative's rights relative to the withdrawn letters. Nor is there any reasonable expectation that the alleged violation will recur. CMS has not announced any intention to reenact the previous technical direction letters and has replaced the policy articulated therein with an instruction to Medicare contractors to instead institute a manual claim-by-claim review process based on the reasonable and necessary standard. *See, e.g.*, *National Black Police Ass'n*, 108 F.3d at 349 (distinguishing cases in which such assertions had been made).

B. There is no merit to Regenative's arguments before the district court that the voluntary-cessation exception to mootness pertains here or that the original alleged violation remains in effect. *See* Dkt. No. 25, at 23-27.

When assessing the voluntary-cessation exception in the context of a suit against governmental (rather than private) parties, courts apply a general presumption that the government is not acting with malicious intent. "At least in the absence of overwhelming evidence (and perhaps not then)," this Court has emphasized that "it would seem inappropriate for the courts either to impute such manipulative conduct to a coordinate branch of government, or to apply against that branch a doctrine that appears to rest on the likelihood of a manipulative purpose." *Clarke v. United States*, 915 F.2d 699, 705 (D.C. Cir. 1990) (en banc). This Court thus has found the voluntary cessation doctrine to be inapplicable where the intervening government action occurred before an adverse decision and therefore was not trying to "erase an unfavorable decision from the books." *National Black Police Assn*, 108 F.3d at 352.

Those precedents apply in full force here. CMS swiftly rescinded its February 2022 instructions to automatically deny claims for HCT/P products in a March 2022 letter instructing Medicare contractors to instead assess such claims on a case-by-case basis under the reasonable and necessary statutory standard (including by reopening denials that had issued pursuant to the prior

letters). *See* JA 211. That recission was not in response to any adverse decision from the district court; indeed, the district court subsequently agreed with CMS that it lacked subject-matter jurisdiction over Regenative's suit. There thus is no reason to apply the voluntary cessation doctrine here.

Nor can Regenative's bald assertions that Medicare contractors have ignored this recission revive its claim. *See* JA 110-11, ¶ 11; JA 127-29, ¶¶ 108-119; *see also* Pl.'s Br. 8-9. The conclusory allegations that CMS has fraudulently asserted that its policies were rescinded while secretly instructing Medicare contractors to continue to automatically deny such claims are insufficient even at the motion to dismiss stage. *See Iqbal*, 556 U.S. at 678; *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). Regenative's assertions that one unidentified provider spoke to one unidentified employee of one Medicare contractor "[i]n mid-April" 2022, who allegedly stated that the first two letters were still in force, cannot be extrapolated into the vast web Regenative spins out. *See* JA 127-29, ¶¶ 108-119. Even taken as true, one potentially confused employee speaking a few weeks after the third technical direction letter does not represent the views of that Medicare contractor, much less all the Medicare contractors or the Secretary.

And Regenative's other allegations about providers' experiences cannot be squared with its theory. Regenative has alleged that Medicare contractors

are requesting that providers "submit impossible-to-obtain documentation for claims." *See* JA 128, ¶ 117; *see also* Pl.'s Br. 22 (arguing that "it is impossible for providers to submit reimbursement claims due to the [Medicare contractors'] required documentation"). But this undermines Regenative's claim that an automatic denial policy still applies: if Medicare contractors were automatically denying all claims, then there would be no need for the contractors to request documentation to substantiate the claims as part of a claim-by-claim analysis. And, of course, as explained, those providers can raise objections to any such documentation requirements as part of the administrative appeals process that can culminate in judicial review.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ABBY C. WRIGHT

/s/ Caroline D. Lopez
CAROLINE D. LOPEZ
Attorneys, Appellate Staff
Civil Division, Room 7535
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-4825
caroline.d.lopez@usdoj.gov

Of Counsel:

SAMUEL R. BAGENSTOS
General Counsel

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation

JULLIA CALLAHAN BRADLEY
Attorney
U.S. Department of Health and Human Services

June 2023

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,370 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Calisto MT 14-point font, a proportionally spaced typeface.

/s/ Caroline D. Lopez
Caroline D. Lopez

CERTIFICATE OF SERVICE

I hereby certify that on June 7, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ Caroline D. Lopez
Caroline D. Lopez

ADDENDUM

TABLE OF CONTENTS

42 U.S.C. § 405(g), (h)

§ 405. Evidence, procedure, and certification for payments

****

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia.****

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

****

ORAL ARGUMENT NOT YET SCHEDULED

No. 23-5020

UNITED STATES COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA CIRCUIT

ROW 1 INC. D/B/A REGENATIVE LABS,

Appellant

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, SOLELY IN HIS OFFICIAL CAPACITY; ET AL.,

Appellees

On Appeal from the Order and Opinion of the United States District Court for the District of Columbia, Case No. 22-cv-0718, dated January 12, 2023

Reply Brief of Appellant Row 1 Inc. d/b/a Regenative Labs

BRIAN H. PANDYA
FREDERICK R. BALL
ROBERT M. PALUMBOS
DUANE MORRIS LLP
901 New York Ave. NW, Suite 700-East
Washington, DC 20001
(202) 776-7800

Counsel for Appellant
Row 1 Inc. d/b/a Regenative Labs

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

GLOSSARY

CMS	Centers for Medicare & Medicaid Services
HCT/P	Human Cells, Tissues, or Cellular or Tissue-based Products
HHS	Department of Health & Human Services
MAC	Medicare Administrative Contractor
TDL	Technical Direction Letter

SUMMARY OF ARGUMENT

Contrary to what the Government argues, Regenative's complaint is fundamentally that the Government changed its policies and substantive legal standards without abiding by required notice-and-comment procedures. This is not a case about claims reimbursement, as the Government wants the Court to believe. This case is about the Government covertly issuing sub-regulatory directives to government contractors regarding the use of HCT/P products with the net effect of disparaging Regenative's products.

Cognizant of the impact that CMS pronouncements have on the entire healthcare sector, the Medicare statute includes notice-and-comment rules more stringent than those included in the Administrative Procedure Act. *See Azar v. Allina Health Services*, 139 S. Ct. 1804, 1809, 1811 (2019). As in *Allina*, because the Government "neglected its statutory notice-and-comment obligations," it has substantially "[a]ffected members of the public [who] received no advance warning and no chance to comment first . . . ." *Allina*, 138 S.Ct at 1808. The Government's failure to follow statutorily required notice-and-comment procedures is particularly harmful in the situation presented in this case.

The required notice-and-comment process is *the* opportunity the Medicare statute provides to Regenative to challenge the Government's unlawful and improper

Policy. Regenative is neither a provider nor a beneficiary, so it has no access to the administrative appeals process.[1]

The Government's actions here stole from Regenative any opportunity to provide input into the Government's substantive changes in policy—precisely the opportunity the notice-and-comment requirement is intended to provide. Contrary to what the Government argues, Regenative has no opportunity other than a lawsuit to challenge the process by which the Government secretly changed the substantive legal standard to be applied to Regenative's products.

Regenative addresses four arguments here. *First*, the district court erred by applying 42 U.S.C. § 405(h) to bar Regenative's causes of action. On its face, Section 405(h)'s prohibition against actions to "recover on any claim" under the Medicare Act does not apply to a cause of action seeking to vindicate an interest in procedural regularity that is not a claim for money, reimbursement, benefits, or program eligibility. The Government's argument that Regenative's causes of action are "inextricably intertwined" with reimbursement claims confuses the wrongful act in this case with one of the resulting harms. It also fails to recognize that the Government's improper Policy has harmed Regenative by effectively rendering its

[1] In fact, had the Government properly engaged in notice-and-comment rulemaking, not acted outside its statutory authority, and not acted arbitrarily and capriciously, Regenative's need to bring this lawsuit may have been obviated.

products unmarketable even to private payors, let alone to federal program beneficiaries. Further, the Government's attempts to misconstrue Regenative's requested relief ignore that Regenative seeks merely to reestablish the pre-Policy status quo.

Second, even if Section 405(h) applied to Regenative's causes of action, the district court erred by holding that the "no review at all" exception to the channeling requirement is inapplicable. No proxies exist sufficiently incentivized to challenge the Government's failure to follow notice-and-comment procedures, and none of the cases the Government cites involve causes of action alleging such a failure. All that is required at this stage is well-pled facts supporting Regenative's allegations that no proxies exist. Regenative has pled such facts.

Third, the district court erred by holding that it lacked subject matter jurisdiction under the Mandamus Act, 28 U.S.C. § 1361. Regenative has a clear right to relief, and the Government has a clear duty to act, both with respect to the Government's requirement to adhere to notice-and-comment procedures and with respect to its failure to do so. Regenative also has adequately pled that it has no access to the Medicare administrative appeals process, making judicial relief its only option. These well-pled facts satisfy all three elements of the Mandamus Act. At this stage, well-pled facts are all that Regenative must provide. Finally, in the event that Section 405(h) bars jurisdiction over Regenative's claims, the equities weigh in

favor of mandamus jurisdiction because Regenative has suffered substantial harm by way of the Government's Policy, harm that can be rectified only through mandamus relief. Under the Government's interpretation of Section 405(h), if mandamus jurisdiction is not allowed, the Government will be free from any meaningful challenge to any substantive rules that it issues via "policy" changes without notice and comment.

Fourth, this case is not moot because Regenative has adequately alleged that the Government's Policy remains in effect. Nothing more is needed to survive a motion to dismiss. Further, even if the Government had ceased its Policy, it did so voluntarily, and voluntary cessation of improper conduct will not moot a case unless a defendant meets the heavy burden of showing that the challenged conduct cannot resume—a burden the Government has not met.

ARGUMENT

1. The district court erred by holding that it lacked subject matter jurisdiction under 42 U.S.C. § 405 (h) because Regenative does not seek "to recover on any claim arising under" the Medicare Act.

Section 405(h) does not apply to Regenative's claims because Regenative does not seek "to recover on any claim" for benefits, reimbursement, or any payment, whether monetary or otherwise. The Government asserts several arguments in support of the district court's erroneous interpretation of 42 U.S.C. § 405(h). However, it fails to rebut that the phrase "to recover on any claim" arising

under the Medicare Act, by its plain language and by the very name of Section 405 ("Evidence, procedure, and certification for payments"), relates only to the processing of individual reimbursement claims for services or goods provided under the Medicare Act. Section 405(h) thus does not prohibit causes of action brought by parties seeking to vindicate an interest in procedural regularity.

Contrary to the Government's mischaracterization of Regenative's complaint as being one for reimbursement, Regenative's causes of action allege that the Government enacted this Policy without adhering to procedural requirements, particularly the notice-and-comment requirement. *Compare* Appellees' Br. 17 ("[A]t bottom, [these claims] seek reimbursement for beneficiaries and providers"), *with* JA111, at Am. Compl. ¶ 12 ("Defendants' Policy: (1) is arbitrary and capricious . . . ; (2) exceeds its statutory authority; (3) contradicts Congressional intent, and (4) violates procedural requirements . . . ."). This requirement was enacted by Congress specifically to protect interested stakeholders such as Regenative. *Allina*, 139 S. Ct at 1809.[2] The Government's interpretation of Section 405(h) would mean the Government's shadow Policy—sub-regulatory guidance formed in contravention of the Medicare Act's clear, stringent notice-and-comment requirements—would be

[2] Congress has dealt with the Government's dislike of following the requirements of notice-and-comment rulemaking before and specifically rejected it. *Allina*, 139 S. Ct. at 1809.

free of judicial scrutiny, as Regenative would have no opportunity to raise its causes of action. Congress does not freely extinguish all avenues of judicial review, and the Government fails to carry its burden of showing that Congress intended to keep parties like Regenative (who cannot bring administrative appeal claims for reimbursement) out of court. *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986).

The differences between this case and the cases that the Government relies on highlight why the district court erred. The Government relies on *Heckler v. Ringer*, 466 U.S. 602 (1984), to argue that Regenative's claims are "'inextricably intertwined' with [a] claim for benefits" but ignores that (a) the plaintiffs in *Ringer* were Medicare beneficiaries who had direct access to the administrative appeals process, (b) the plaintiffs sought to recover payments by challenging the claims-processing methodology, and (c) therefore, the claims were "inextricably intertwined" with the beneficiaries' claims for benefits. Appellees' Br. 24-25 (citing *Ringer*, 466 U.S. at 615). Here, Regenative is not a Medicare beneficiary (or provider), has no access to the administrative appeals process, and is not seeking claims for benefits or reimbursement, so its causes of action cannot be "inextricably intertwined" with any claims for benefits or reimbursement. JA29, at Compl. ¶ 93; JA133-34, at Am. Compl. ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief.

The Government similarly relies on *Three Lower Counties Community Health Services, Inc. v. United States Department of Health & Human Services*, 317 F. App'x 1, 2-4 (D.C. Cir. 2009) (per curiam), ignoring that the case involved a claim from a "provider" directly challenging cost limits to its reimbursement payments.[3] Appellees' Br. 26, 31 (citing *Three Lower Ctys.*, 317 F. App'x at 2-4). Regenative is not a provider with claims for reimbursement payments.

The Government also relies heavily on *RICU LLC v. United States Department of Health & Human Services*, 22 F.4th 1031 (D.C. Cir. 2022), in arguing that Regenative's notice-and-comment claims have already been ruled by this Court as being barred by Section 405(h). Appellees' Br. 27-28 (citing *RICU*, 22 F.4th at 1035-39). The Government, however, fails to address the fact that in *RICU*, the Government published and adopted regulations following lawful rulemaking. *RICU*, 22 F.4th at 1033. The plaintiff in *RICU* was a healthcare services provider who sought predetermination eligibility under regulations otherwise not being

[3] The out-of-circuit cases Appellees rely on are similarly distinguishable. In *Fanning v. United States*, 346 F.3d 386, 401 & n.16 (3d Cir. 2003), the plaintiffs were a class of beneficiaries directly challenging a reimbursement decision. In *Kaiser v. Blue Cross of California*, 347 F.3d 1107, 1112 & n.2 (9th Cir. 2003), the plaintiffs were providers seeking relief from a rule to obtain reimbursement. Here, Regenative is neither a provider nor a beneficiary asserting a claim for payment, benefits, or eligibility; rather, Regenative's claims seek solely to restore the status quo and require Appellees to abide by the notice-and-comment rulemaking requirements. JA29, at Compl. ¶ 93; JA133-34, ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief.

challenged. *Id.* at 1034. Regenative, by contrast, is a manufacturer who seeks relief from the Government's failure to follow notice-and-comment procedural requirements and its use of improper, sub-regulatory, covert TDLs. JA111, at Am. Compl. ¶¶ 12; JA133-34, at Am. Compl. ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief. Regenative has no opportunity for an eligibility determination at any stage and instead seeks a return to the pre-Policy status quo. Section 405(h) does not preclude such claims.

The Government argues that "settled precedent" has rejected "a distinction that limits the scope of § 405(h) to claims for monetary benefits." Appellees' Br. 26 (citing district court Order and quoting *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 14 (2000)). This selectively quoted text omits the important subsequent portion from the Supreme Court's holding, which lists the types of claims that fall within Section 405(h), particularly "[c]laims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy." *Illinois Council*, 529 U.S. at 14. Regenative asserts no claims that fall within these examples.

The Government misconstrues Regenative's amended complaint, asserting that the "crux of Regenative's amended complaint is" the Government's failure to reimburse providers' claims for Regenative's products. Appellees' Br. 22-23. This assertion confuses the wrongful act with one of the resulting harms. The wrongful

act from which Regenative seeks relief is the Government's enactment of the Policy without the requisite notice-and-comment and in an unlawful and arbitrary and capricious manner. JA133-34, ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief. One of the resulting harms is the Policy's effect of causing providers—whether Medicare providers or otherwise—to stop using Regenative's products due to the mischaracterization of those products. JA30, at Compl. ¶ 103; JA129, at Am. Compl. ¶ 124. The crux of the amended complaint is thus not inextricably intertwined with a claim for reimbursement or benefits.

It is implausible that Congress intended no judicial review at all of Regenative's causes of action to challenge the manner in which the Government has flouted its obligations in implementing the Medicare statute. *See Michigan Academy*, 476 U.S. at 681. The strong presumption courts must follow is that "Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command." *Id.*

The intervening decision in *Illinois Council* that the channeling provision of 42 U.S.C. § 405(h) extends to Medicare providers in the same way as claims by Medicare patients, 529 U.S. at 16, does not lead to the conclusion that Regenative's cause of action is channeled. The Government asserts that such access bars Regenative from proceeding with this lawsuit. *See* Appellees' Br. 21. But

Regenative is neither a Medicare patient nor a Medicare provider. Regenative thus has no access to the administrative appeals process under the Medicare statute, so the courts are its only avenue for relief given CMS's failure to follow notice-and-comment procedures. *Illinois Council*, 529 U.S. at 44 ("Our constitutional structure contemplates judicial review as a check on administrative action that is in disregard of legislative mandates or constitutional rights.") (Thomas, J. dissenting).

The Government's response relies on a single line in the prayer for relief in Regenative's amended complaint, which requests among other forms of relief that the Court declare that Regenative's products are Section 361 products and "should be reimbursed **as such to maintain the status quo**." Appellees' Br. 24 (quoting JA135, at Am. Compl. Prayer for Relief ¶ 1(1)(iii)) (emphasis added). Importantly, Regenative does not seek an order, as the Government would have the Court believe, requiring that its products be reimbursed. Appellees' Br. 49. Regenative does not seek to recover on any claim for reimbursement or benefits. Regenative similarly does not request any new reimbursement determination. Rather, Regenative simply requests that the Court vacate the Government's unlawfully enacted Policy and revert back to the pre-Policy status quo. JA133-34, at Am. Compl. ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief. This status quo must remain unless and until the Government engages in proper notice-and-comment rulemaking, at which

time Regenative, and any other stakeholders, can submit comments, and CMS can then respond in a comprehensive and cogent manner.

The Government's arguments concerning the Medicare reimbursement of Regenative's customers wholly ignore the many other non-Medicare doctors who no longer use Regenative's products because of the Policy. *See* Appellees' Br. 21-33. The Government ignores Regenative's allegations that the Policy has portrayed Regenative's products as being potentially unsafe, ineffective, and marketed and promoted illegally. Appellees' Br. 32-33; *see also* JA184-JA215, at Am. Compl. Exhs. C-E (repeating the "illegally marketed" language across numerous documents). This deception has caused non-Medicare/Medicaid, self-pay, and cash payment providers to stop using Regenative's products. JA129, at Am. Compl. ¶ 124. Regenative's claim is thus not strictly related to Medicare providers.

The Government also concedes that its Policy states that products such as Regenative's would not be reimbursed by Medicare because they "have not been proven to be safe and effective." *See* Appellees' Br. 11, 32. This harm to Regenative's products has caused damage outside of and beyond Medicare reimbursement by suggesting that Regenative's products are not allowed to be marketed or used under Federal law. JA129, at Am. Compl. ¶ 124. The Government's faux-slippery slope counterargument to this point is a strawman, because the Policy causes reputational harm not simply by requiring a blanket denial,

but rather, by improperly alleging that Regenative's products are not safe and effective. Appellees' Br. 33; JA129, at Am. Compl. ¶ 124. That aspersion cast on Regenative's products impacts not only reimbursement but also the general impression providers and patients have of Regenative's products. As discussed in Regenative's Brief, HHS, CMS, and their MACs are neither qualified nor authorized to determine what is safe and effective. Br. of Appellant 2-3. Therefore, since Regenative seeks relief to address this improper overreaching and *not* to address any claims for payment, Section 405(h) does not bar Regenative's suit.

2. The district court erred by refusing to apply an exception to Section 405(h) under the facts pled in this case.

Even if Section 405(h) did apply to Regenative's causes of action (it does not), Regenative's particular challenges fall within exceptions to Section 405(h)'s channeling requirement. As alleged, no provider is adequately incentivized to bring *these particular causes of action* via the administrative process. JA111, at Am. Compl. ¶ 12; JA128-JA129, at Am. Compl. ¶¶ 117, 123. The Government overextends *Council for Urological Interests v. Sebelius*, 668 F.3d 704 (D.C. Cir. 2011), to assert that proxies need not be sufficiently incentivized to raise Regenative's "particular claims." Appellees' Br. 42. However, the case stands for the unremarkable proposition "the *Illinois Council* exception is primarily concerned with whether a particular *claim* can be heard through Medicare Act channels."

Council for Urological Interests, 668 F.3d at 712 (emphasis in original). Here, no proxies exist to assert Regenative's particular causes of action.

The Government's citation to a recently-filed complaint further supports Regenative's argument. The cited complaint includes no allegations that any provider asserted the particular claim that the Policy was improperly enacted without notice and comment. *See* Appellees' Br. 43 (citing Complaint at 50-54, 57, *Greiner Orthopedics, LLC v. Becerra*, No. 1:23-cv-01047 (D.D.C. Apr. 14, 2023)). Moreover, the Government cannot argue that *Greiner* is related to Regenative's case and simultaneously certify that *Greiner* is not related. *Compare* Appellees' Br. ii (certifying that apart from *StimLabs, LLC v. Becerra*, No. 22-cv-01988 (APM), 2022 WL 13840218 (D.D.C. Oct. 21, 2022), the Government is "unaware of any other related cases"), *with* Appellees' Br. 43 (citing Complaint at 50-54, 57, *Greiner*, No. 1:23-cv-01047) (arguing that *Greiner* involves providers "rais[ing] the types of arguments that Regenative raises" over "the [same] policy challenged here"). Only Regenative can and will bring and fully pursue the cause of action that the Government's failure to follow statutorily required notice-and-comment procedures unlawfully portrayed Regenative's products as being potentially not safe and effective.

To argue otherwise, the Government again discards *Council for Urological Interests* and relies on *RICU*, ignoring that the plaintiff in *RICU* sought a

predetermination of benefits for its providers and that the regulation at issue in *RICU* was promulgated using notice-and-comment procedures. Appellees' Br. 35, 36-37; *RICU*, 22 F.4th at 1033. Those claims could have been submitted to Medicare and then, upon being denied, brought through the Medicare administrative appeals process. Here, Regenative does not seek any predetermination of benefits—Regenative has no opportunity for any determination of benefits—but instead seeks the *vacatur* of a harmful and unlawful Policy that was improperly enacted without notice and comment. JA133-34, at Am. Compl. ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief.

Council for Urological Interests thus presents the facts most similar to this present case. This Court has held that a plaintiff qualifies for the *Illinois Council* exception "not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court." *Council for Urological Interests*, 668 F.3d at 712. "[T]he *Illinois Council* inquiry is fundamentally a practical one," and a court should analyze "factors that speak to a potential proxy's *willingness and ability* to pursue the plaintiff's [particular] claim." *Id.*[4]

[4] Appellees turn to out-of-circuit cases to avoid *Council for Urological Interests*; however, those cases do not support Appellees' position. In *Sensory NeuroStimulation, Inc. v. Azar*, 977 F.3d 969, 983 (9th Cir. 2020) (emphasis added), the court held that the channeling exception "does not apply where another party is able to pursue the **same claim** through an appropriate administrative channel and is

This present matter proceeded only to the pleading stage. Contrary to the Government's assertions, Regenative is not required to submit affidavits or any evidence that providers and beneficiaries either have stopped purchasing its products or are not incentivized to pursue Regenative's particular claims. Appellees' Br. 42. Regenative has already sufficiently and plausibly alleged in a verified complaint (1) that providers will simply choose not to purchase and use Regenative's products that CMS and the MACs state are "illegally marketed," improperly used, and not "safe or effective," (2) that providers will use alternative treatments instead of Regenative's products, and (3) that it is impossible for providers to submit reimbursement claims due to the MACs' documentation requirements; further, it has argued with supporting precedent that Regenative has not sought to have a provider assign its claim because of the possible implications of the Anti-Kickback Statute. *See* JA184-JA215, at Am. Compl. Exs. C-E (repeating the "illegally marketed" language across numerous documents); JA129, at Am. Complaint ¶ 123; Mem. of Law in Supp. of Pl.'s Notice of Suppl. Authority Mot. for Oral Hr'g on Defs.' Mot. to Dismiss p. 3 n.1, Dkt. 34-1.

---

incentivized to do so." In *Sensory*, notice-and-comment requirements were not at issue, and the CEO of the plaintiff was actually capable of becoming "aggrieved" and serving as proxy for the particular claims of the company. *Id.* In *National Athletic Trainers' Association v. United States Department of Health and Human Services*, 455 F.3d 500, 507 (5th Cir. 2006), the rule at issue had gone through notice and comment, and plaintiff's proxies were actually identified because they provided comments during the notice-and-comment period.

Indeed, the Government would require Regenative to cast aside prevailing case law and risk violating the Anti-Kickback Statute to obtain an assignment of an administrative claim. *Compare* Appellees' Br. 44, *with Akebia Therapeutics, Inc. v. Becerra*, 548 F. Supp. 3d 274, 286 n.15 (D. Mass 2021). Even to ask Regenative to go through the impossible task of getting assignment of an administrative appeal for somebody else's claim would not resolve the problem. All a Medicare provider can do is request reimbursement and, if denied, then file an administrative appeal asking again for reimbursement. *See* 42 C.F.R. § 405.900(b) (affirming that the administrative appeals process concerns only "appeals of initial determinations for benefits"). But Regenative's complaint is not about reimbursement denials. Regenative's complaint is about the Government's failure to adhere to notice-and-comment requirements in promulgating a Policy that improperly and unlawfully treats Regenative's HCT/Ps as purportedly being "illegally marketed" and not safe and effective. JA129, at Am. Compl. ¶ 124; JA133-34, at Am. Compl. ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief. Taking assignment of one or one hundred reimbursement appeals would not address that fundamental injustice. At this stage, Regenative's allegations must be accepted as true, a standard the district court violated. *Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011).

The Policy is not merely a denial of reimbursement. By issuing this Policy, the Government has essentially rendered Regenative's products tainted in the

marketplace. JA111, at Am. Compl. ¶ 12; JA129, at Am. Compl. ¶ 124; JA135, at Am. Compl. ¶ 135. Regenative challenges CMS and the MACs' failure to follow notice-and-comment procedural requirements. JA111, at Am. Compl. ¶¶ 12. No adequate proxy exists to fully pursue this particular cause of action.

Accordingly, the district court erred in refusing to apply the *Illinois Council* exception to 42 U.S.C. § 405(h)'s jurisdiction-stripping provisions under the facts pled in this case, and therefore, the district court's order should be reversed.

3. The district court erred by holding that it lacked subject matter jurisdiction under the Mandamus Act, 28 U.S.C. § 1361.

The district court has mandamus jurisdiction here because Regenative can show: (1) a clear and indisputable right to relief; (2) that CMS is violating a clear duty to act; and (3) that no adequate alternative remedy exists. *Am. Hospital Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016).

Regenative has sufficiently alleged that it has a clear right to relief and that the Government has a clear duty to act. JA111, at Am. Compl. ¶ 12; JA130-JA132, at Am. Compl. ¶¶ 131-33; JA134, at Am. Compl. ¶ 142. The Government's key counterargument is that CMS purportedly rescinded its improper Policy by issuing a third TDL to its MACs. Appellees' Br. 48-51. This argument, however, ignores entirely Regenative's allegations that the Government has **not** rescinded its improper Policy, instead issuing a faux-rescission for purposes of this litigation. JA126, at Am. Compl. ¶¶ 105-06; JA129, at Am. Compl. ¶ 120. Regenative has sufficiently

alleged that the Policy continues in full force. JA110-JA111, at Am. Compl. ¶ 11; JA126-JA129, at Am. Compl. ¶¶ 107-19.

The Government continues the theme of misrepresenting Regenative's allegations when it turns a blind eye to the requirement to follow notice-and-comment rulemaking. *See* Appellees' Br. 48-51 (arguing that no rights or duties exist but failing even to mention notice-and-comment requirements). Here, the Government cannot and does not attempt to meaningfully rebut the fact that CMS has an obligation to follow statutorily required notice-and-comment procedures when adopting a new policy or substantive legal change, including the Policy. 42 U.S.C. §§ 1395hh(a)(1)-(3) and (b)(1); 405(a). Regenative does not contend (as the Government argues) that CMS had an obligation to issue a new Policy. Appellees' Br. 49. If CMS had not issued the revamped Policy in February 2022, presumably everyone would still be operating under the status quo that existed prior to CMS covertly issuing the Policy, under which Regenative's products were typically reimbursed and not automatically denied. But CMS *did* issue a new Policy. JA122, at Am. Compl. ¶ 81. And at that point, CMS *did* have a ministerial obligation to publish the new Policy and to go through the statutorily required notice-and-

comment procedures. JA130-JA132, at Am. Compl. ¶¶ 131-33; JA134, at Am. Compl. ¶ 142.[5]

Similarly, Regenative has no alternative adequate remedy available to it because it has no access to the administrative appeals process. Judicial relief is the only option open to Regenative. JA29, at Compl. ¶ 93. The Government argues that Regenative's alternative adequate remedy is Medicare's administrative appeals process—ignoring that Regenative itself has no access to it. Appellees' Br. 46-48; JA29, at Compl. ¶ 93. The Government would bar Regenative from mandamus jurisdiction for the same reason it would bar Regenative from Section 405(h) jurisdiction, despite Section 405(h) not being a bar itself to mandamus jurisdiction. The Government also fails to address the case law within this Circuit holding that exhausting the administrative process is not a prerequisite to jurisdiction for causes of action challenging failures of CMS to follow required administrative procedures. *See Helomics Corp. v. Burwell*, No. CV 16-546 (RMC), 2016 U.S. Dist. LEXIS 47803, at *14 (D.D.C. April 8, 2016).

[5] Regenative suspects the Government recognized the merits of the initial complaint and, in an attempt to avoid needing to defend its actions, attempted to moot the litigation. Unfortunately, that attempt merely compounded the government's failure to engage in notice-and-comment rulemaking: because the original TDLs had to go through notice and comment, any subsequent revisions must go through the same. *Montefiore Med. Ctr. v. Leavitt*, 578 F. Supp. 2d 129, 134 (D.D.C. 2008).

The Government similarly fails to address the clear case law that mandamus jurisdiction is available "to review otherwise unreviewable procedural issues" that are "unrelated to the merits of the benefits claim." *Wolcott v. Sebelius*, 635 F.3d 757, 765-66 (5th Cir. 2011); *see also Samaritan Health Ctr. v. Heckler*, 636 F. Supp. 503, 508-11 (D.D.C. 1985); *Cockrum v. Califano*, 475 F. Supp. 1222, 1225, 1229, 1230-31 (D.D.C. 1979). Here, Regenative's causes of action relate solely to procedural issues (i.e., the failure to adhere to notice-and-comment requirements and the resulting promulgation of a Policy misclassifying Regenative's products) and not to any "benefits claim." JA133-34, at Am. Compl. ¶¶ 136, 138, 143; JA134-35, at Am. Compl. Prayer for Relief. Regenative has no alternative remedy to address these issues. JA29, at Compl. ¶ 93.

Finally, the Government argues that although not addressed by the district court, Regenative has not shown that the equitable case for mandamus relief clearly weighs in its favor—with the main thrust of its argument being that "the challenged policy is no longer extant." Appellees' Br. 51-52. Again, try as it may, the Government cannot escape or delete from existence Regenative's allegations that the Policy has not actually been rescinded and remains in full force and effect. JA110-JA111, at Am. Compl. ¶ 11; JA126-JA129, at Am. Compl. ¶¶ 105-20. The equitable case for Regenative is clear. Without jurisdiction and the ability to

challenge the improper Policy, CMS will be free to issue shadow rules and policies, unbound by notice and comment or any other procedural safeguard.

Indeed, CMS covertly issued the Policy challenged here through TDLs provided only to the MACs and not made generally available. JA121, at Am. Compl. ¶¶ 76, 78. Regenative first received the February 2022 TDLs *after* filing its initial complaint and requesting copies of any such policy letters from counsel in the litigation. JA110, at Am. Compl. ¶ 11.

CMS and the MACs cannot be allowed to abuse Section 405(h) and to hide behind it to issue shadow rules and policies that have potential to shut down businesses and deny care to patients. Mandamus jurisdiction exists to address precisely this kind of exceptional circumstance. The equitable considerations for mandamus jurisdiction clearly weigh in favor of Regenative.

Accordingly, the district court erred in holding that it did not have jurisdiction to issue a writ of mandamus ordering the Government to comply with required administrative rulemaking procedures.

4. The Government's argument that its alleged voluntary cessation of the policy moots Regenative's claims is contrary to well-pled facts and established law.

The Government asserts an argument not addressed by the district court in its Order and Opinion, that Regenative's claims are moot because the Government has

allegedly voluntarily rescinded the Policy.[6] Appellees' Br. 52-82. Not only does the Government's argument contradict Regenative's allegations that the Policy has not been rescinded; it also ignores Supreme Court precedent that a party's voluntary of a practice cessation does not moot a challenge to that practice, particularly where the conduct is possible to recur. JA126, at Am. Compl. ¶¶ 105-06; JA129, at Am. Compl. ¶ 120; *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Hum. Res.*, 532 U.S. 598, 609 (2001).

First, the Government cannot rewrite or ignore Regenative's allegations. In evaluating a motion to dismiss under either Rule 12(b)(1) or Rule 12(b)(6), "the Court must treat the complaint's factual allegations as true and must grant plaintiff the benefit of all inferences that can be derived from the facts alleged." *Nat'l Harbor GP, LLC v. Gov't of the D.C.*, 121 F. Supp. 3d 11, 16 (D.D.C. 2015) (quoting *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1113 (D.C. Cir. 2000)) (internal ellipses and quotation marks omitted). Regenative acknowledges that CMS issued a March 25, 2022, TDL to the MACs purporting to revoke the Policy; however,

[6] Appellees also argue only in a footnote that should this Court remand the case back to the district court, the MACs should be dismissed because they are not the real parties in interest. Appellees' Br. 53 n.3. Such a dismissal would be premature because if the Policy has actually been rescinded (Regenative has sufficiently alleged that it has not), then the MACs must be acting with reckless disregard and thus subject to this lawsuit. 42 U.S.C. § 1395kk-1(d); *Rochester Methodist Hosp. v. Travelers Ins. Co.*, 728 F.2d 1006, 1012 (8th Cir. 1984).

Regenative sufficiently and plausibly alleges that despite these TDLs, CMS's Policy continues in full force and has not been rescinded. JA110-JA111, at Am. Compl. ¶ 11; JA126-JA129, at Am. Compl. ¶¶ 105-20. Specifically, Regenative alleges that CMS's Policy continues to require all liquid tissue products to be automatically denied, the same requirement that has been in place since February 2022. JA110-JA111, at Am. Compl. ¶ 11; JA127-JA128, at Am. Compl. ¶¶ 108-14. Regenative has sufficiently alleged that CMS's Policy has not been rescinded, and thus its claims are not moot.

Second, the Supreme Court has held that a party's voluntary cessation of an unlawful practice will usually not moot its opponent's challenge to that practice. *See, e.g.*, *Buckhannon*, 532 U.S. at 609; *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287-89 (2000). "[A] defendant cannot automatically moot a case simply by ending its unlawful conduct once sued"; otherwise, a litigant could defeat a lawsuit by temporarily ceasing its unlawful activities, with nothing to stop the litigant from reengaging in the unlawful behavior after the dismissal. *See Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013).

Here, the Government acknowledges that it abandoned the Policy voluntarily, apparently also conceding that those TDLs were unlawful. Appellees' Br. 57. The Government, however, rescinded the TDLs only *after* Regenative filed its complaint, in a thinly veiled attempt to divest the district court of jurisdiction and to try to avoid

litigation wherein it would need to defend its unlawful and improper rulemaking. JA 109, at Am. Compl. ¶ 10. Putting aside the fact that Regenative has alleged that the conduct has not ceased, which is fatal to the Government's argument, nothing would prevent the Government from engaging in the same unlawful behavior if this case were dismissed—and the Government does not meaningfully argue that it is so prevented. The reliance by the Government on *National Black Police Association v. District of Columbia*, 108 F.3d 346, 352 (D.C. Cir. 1997), is misplaced, as that case involved a defendant's "legislative efforts to repeal [the regulation at issue, efforts that] had been ongoing for over two years . . . [including] even before this litigation was filed." Appellees' Br. 53-56 (citing *Nat'l Black Police Ass'n*, 108 F.3d at 349). It is clear here that the Government's faux-rescission was executed only as an attempt to hide behind Section 405(h) and avoid a binding ruling from the Court that its Policy is unlawful.

The Government's attempt to minimize Regenative's allegations that there has been no rescission is merely another attempt to rewrite Regenative's amended complaint. *See* Appellees' Br. 56-58. Regenative alleged (and the Government's actions since the amended complaint was filed reinforce) that the Policy remains in full force, with blanket denials continuing to be given for Regenative's products, as was expressly confirmed by one of the MACs. JA110-JA111, at Am. Compl. ¶ 11; JA126-JA129, at Am. Compl. ¶¶ 107-19. The Government's unsupported argument

that this confirmation from a MAC was "one potentially confused employee" has no bearing here. Appellees' Br. 57. That allegation, for which Regenative has a lawfully obtained recording and transcript, is the *only* allegation before the Court regarding a specific interaction between a MAC and a Medicare provider.

Especially at the motion to dismiss stage, the Government cannot insulate itself from judicial scrutiny by passing off that substantiated and verified allegation as being nothing more than "one confused employee." Further, in this faux-rescission exists the practical relationship between CMS and the MACs, where even if not technically binding, the MACs as regulated entities have strong incentives to adhere to sub-regulatory or shadow guidance.

> If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding."

Appalachian Power Co. v. EPA, 208 F.3d 1015, 1021 (D.C. Cir. 2000). And thus, even where the guidance contains language disclaiming binding effect, courts generally understand that such language is "boilerplate"—even a "charade, intended to keep the proceduralizing courts at bay." *Id.* at 1023.

The Government does not meet the "'heavy burden of persuading' the court that the challenged conduct cannot reasonably be expected to start up again."

Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167, 189 (2000) ; *see also* Appellees' Br. 55. Nor can the Government satisfy the requirement that the effects have been irrevocably eradicated where Regenative has alleged that even after the March 25, 2022, Letter, the Government's "automatic denial of Regenative's products [and the] 'Policy itself, for those injections, remain[] the same.'" JA110, at Am. Compl. ¶ 11.

Accordingly, the voluntary cessation exception to the mootness doctrine applies here, and Regenative's claims are not moot.

CONCLUSION

The dismissal order of the district court should be vacated and the case remanded for further proceedings.

Respectfully submitted,

Date: June 28, 2023

/s/ Brian H. Pandya
Brian H. Pandya
DUANE MORRIS LLP
901 New York Ave. NW, Suite 700E
Washington, DC 20001
Tel: 202.776.7800
Email: BHPandya@duanemorris.com

Frederick R. Ball
DUANE MORRIS LLP
100 High Street, Suite 2400
Boston, MA 02110-1724
Tel: 857.488.4229
Email: FRBall@duanemorris.com

Robert M. Palumbos
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103-4196
Tel: 215.979.1111
Email: RMPalumbos@duanemorris.com

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because it contains 6,002 words, excluding the parts of the brief exempted by Circuit Rule 32(e)(1).

This brief complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

/s/ Brian H. Pandya

CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2023, I served a true and correct copy of the foregoing on all counsel of record in this action via ECF.

/s/ Brian H. Pandya