No.

In the Supreme Court of the United States

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

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, SOLELY IN HIS OFFICIAL CAPACITY,
RESPONDENT.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

PATRICK GALLAGHER
Counsel of Record
PC GALLAGHER LAW P.A.
13860 Wellington Trace,
Ste. 38-103
Wellington, Florida 33414
312-498-5411
patrick@pcgallagher.com

LEGAL PRINTERS LLC ● Washington, DC ● 202-747-2400 ● legalprinters.com

QUESTION PRESENTED

Whether 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii, prohibits a medical products manufacturer who cannot pursue the Medicare administrative appeals process from filing a judicial action seeking relief from policies adopted by Center for Medicare and Medicaid Services without any notice and comment.

PARTIES TO THE PROCEEDING

Petitioner in this Court is Row 1 Inc. d/b/a Regenative Labs, who was plaintiff-appellant below.

Respondents are Xavier Becerra, Secretary of the Department of Health and Human Services, in his official capacity only, United States Department of Health and Human Services, Chiquita Brooks-Lasure, Administrator of Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC, Wisconsin Physicians Service Insurance Corporation, Novitas Solutions, Inc., National Government Services, Inc., CGS Administrators, LLC, Palmettos GBA, LLC, and First Coast Service Options, Inc. They were defendant-appellee below.

CORPORATE DISCLOSURE STATEMENT

Under Supreme Court Rule 29.6, Row 1 Inc. d/b/a Regenative Labs hereby states that it has no parent corporations. No publicly held corporation owns 10% or more of the stock of Row 1 Inc. d/b/a Regenative Labs.

RELATED PROCEEDINGS

Row 1 Inc., d/b/a Regenative Labs v. Xavier Becerra, Secretary of Health and Human Services, *et al.*, Case No. 22-cv-0718 (APM) (D.D.C.)

Row 1 Inc., d/b/a Regenative Labs v. Xavier Becerra, Secretary of Health and Human Services, *et al.*, No. 23-5020 (D.C. Cir.)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

IN THE
SUPREME COURT OF THE UNITED STATES
No. 24-____

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

v.
XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, SOLELY IN HIS OFFICIAL CAPACITY
Respondent.

On Petition for a Writ of Certiorari to the United States Court of

---

PETITION FOR A WRIT OF CERTIORARI

Row 1 Inc. d/b/a/ Regenative Labs respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.

OPINIONS BELOW

The Opinion of the court of appeals (App., *infra*, 1a-24a) is reported at 92 F.4th 1138. The opinion of the district court (App., *infra*, 25a-34a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 16, 2024. On May 9, 2024, Justice Roberts extended the time within which to file a petition for a writ of certiorari to and including June 16, 2024. Under Rule 30.1, that time is extended to Monday, June 17, 2024. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The provisions of 42 U.S.C. § 405(h) are reproduced at Pet. App., *infra*, 53a.

STATEMENT OF THE CASE

In February 2022, Centers for Medicare and Medicaid Services (CMS) issued two Technical Direction Letters (TDLs) to the Medicare Administrative Contractors (MACs) directing a change in policy. Pet. App. 41a-52a. Those TDLs implemented a change in CMS policy with respect to certain amniotic and placental tissue-based products. Before these TDLs Medicare claims for human amniotic and placental tissue products were determined under the statutory standard whether the care provided was reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A). CMS changed that policy

through the TDLs by directing the MACs to deny payments for all claims for amniotic and/or placental tissue biologics for injections. Pet. App. 49a. In the second TDL dated February 16, 2022, CMS explicitly directed the MACs to deny any incoming claims for certain specific HCPCS Q codes. Each of the Q codes corresponds to a specific product. The list of products slated for automatic denial includes Q4246 which corresponds to ProText and CoreText, products marketed by Regenative Labs. Pet. App. 43a.

CMS directed this change in substantive policy without implementing a National Coverage Determination (NCD) or Local Coverage Determination (LCD), both of which would have required Notice and Comment, and which would have been the normal procedure for implementing a change on coverage policy, especially a change as drastic as directing that all claims be denied. Not only did CMS decline to go through the required notice and comment process for these TDLs, CMS specifically directed the MACs not to share the information contained in the TDLs outside of their organization. The TDLs further stated that "[N]o national message will be distributed from CMS." Pet. App. 45a, 50a.

Without knowing about the two February 2022 TDLs, Regenative filed the complaint in the underlying case in March 2022 after learning that suddenly provider claims for ProText and CoreText were all being denied by the MACs. In response to the complaint, CMS provided those TDLs to counsel for Regenative. Additionally, approximately ten days after the complaint, CMS issued a third TDL dated

March 25, 2022. Pet. App. 35a-40a. That TDL purported to rescind the two prior TDLs. Pet. App. 36a. Like the first two TDLs, this March 2022 TDL did not go through Notice and Comment and was not publicized outside of CMS and the MACs. It was provided to counsel for Regenative in the context of the underlying lawsuit.

Regenative expected that the March TDL would reflect a substantive acknowledgement of the problems with the first two TDLs and reflect a change back to the status quo before those TDLs were issued. Unfortunately, through feedback from healthcare providers using Regenative's products, it became clear that despite this March 2022 TDL, each of the MACs continued to automatically deny all claims for ProText and CoreText. Regenative thus filed an amended verified complaint challenging implementation of the change in policy without going through the required Notice and Comment process. The basis for jurisdiction in the complaint was 28 U.S.C. 1331, 1361, and 1651.

As a medical products manufacturer, Regenative is not a participant in the Medicare program and has no access to the Medicare appeals process.

The District Court granted Respondent's motion to dismiss for lack of subject matter jurisdiction under 28 U.S.C. § 1331. Pet. App. 27a. The District Court held that Section 405(h) channeled most if not all Medicare claims through the agency review system. Pet. App. 27a. The Court held that this channeling requirement applied under Section 405(h) regardless

of the fact Regenative is unable to assert a claim directly, was challenging a policy not an individual claim, and is seeking only procedural relief. Pet. App. 30a.

The District Court also held that the "no review at all" exception to the channeling requirement did not apply. The Court found that Regenative had not shown there is not an adequate proxy who could raise claims on its behalf through the Medicare administrative appeals process. Pet. App. 31a-32a.

On appeal to the D.C. Circuit, the panel affirmed the dismissal of Regenative's complaint. The panel held that a portion of Regenative's causes of action were moot based on the March 2022 TDL stating that it was rescinding the two February TDLs. Pet. App. 11a-12a. The panel held that the government's abandonment of a challenged policy is the sort of development that can moot an issue. Pet. App. 12a. The panel thus held that the portions of Regenative's causes of action directed at the two February 2022 TDLs were thus moot. Pet. App. 13a.

The panel held that the rest of Regenative's causes of action were barred under 42 U.S.C. 405(h). Pet. App. 14a. According to the panel, "The Supreme Court's capacious understanding of the scope of Section 405(h) bars this action." Pet. Ap. 14a. The panel further held that Appellant's challenge to the procedural irregularity of CMS's policy was not relevant to the analysis of jurisdictional bar under Section 405(h). Pet. App. 15a. The panel acknowledged Regenative's allegations from the

amended verified complaint that the Government did not actually rescind the policy, but rather continues to apply the policy reflected in the two February 2022 TDLs. Pet. App. 16a. The panel found that those harms were inextricably intertwined with claims for Medicare benefits. Pet. App. 16a. The panel also held that the channeling requirement of Section 405(h) barred reputational injury claims because even those claims were intertwined with claims that Regenative's products should be reimbursed. Pet. App. 17a.

The panel also held that the "no-review" exception under *Illinois Council* did not apply. Pet. App. 17a. The panel found that the record suggested there were adequate proxies who could raise similar claims to seek administrative review through the Medicare administrative appeals process. Pet. App. 18a-19a. The panel cited allegations in Regenative's verified complaint that a healthcare provider had called a MAC asking about reimbursement. Pet. App. 20a. The panel also cited a lawsuit filed by providers requesting review of CMS decisions regarding other products. Pet. App. 21a.

REASONS FOR GRANTING PETITION

I. The District of Columbia Circuit's Decision regarding Federal Question Jurisdiction Conflicts with This Court's Precedent.

"[J]udicial 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." *Bowen v. Michigan Academy of Family Physicians,* 476 U.S. 667, 670 (1986) quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140 (1967) (collecting cases).

Under the plain language of the statute and the precedent of this Court, 42 U.S.C. 405(h) does not cut off judicial review of agency action, but rather acts as a channeling mechanism for judicial actions to recover payment for claims on benefits under the Medicare program. *Shalala v. Illinoi Council on Long Term Care*, 529 U.S. 1 (2000) (hereinafter "*Illinois Council*"); *Michigan Academy,* 476 U.S. at 670.

Specifically, Section 405(h) provides that "no action against the United States, … or any officer or employee thereof shall be brought under section 1331 [] of title 28 to recover on any claim arising under this subchapter." Pet. App. 53a.

The channeling mechanism of Section 405(h) does not go so far as to prohibit any action under section 1331 but is limited to actions "to recover on any claim" under the Medicare statute.

In *Michigan Academy*, this Court held that the statute did not go so far as to intend "no review at all of substantive statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." *Michigan Academy*, 476 U.S. at 680.

Consistent with that decision, in *Illinois Council*, this Court held that under *Michigan Academy*, the statute would not foreclose application of the 405(h) bar where its application would preclude judicial review completely rather than channeling judicial review through the applicable agency. 529 U.S. at 17.

In this case, the judgment of the court of appeals conflicts with the precedent of this Court because it completely forecloses judicial review of the causes of action by Regenative Labs against the administrative agency, CMS as a part of the Department of Health and Human Services. Petitioner Regenative Labs has no access to CMS's administrative review process, and thus Regenative has no access to judicial review at all.

Indeed, Regenative cannot file any claim to recover Medicare benefits, as Regenative is not a provider or beneficiary under the Medicare program. The only opportunity for Regenative to raise its causs of action is through the Courts. Regenative's involvement with the Medicare program is not as a participant submitting claims for recovery of benefits.

Contrary to this Court's decisions in *Michigan Academy* and *Illinois Council*, the court of appeals adopted a "capacious" interpretation of Section 405(h) that is contrary to this Court's precedent that the channeling provision of Section 405(h) does not apply where channeling would mean no judicial review at al. *Shalala v. Illinoi Council on Long Term Care*, 529 U.S. 1, 19 (2000) (hereinafter "*Illinois Council*").

This Court has never held that a Plaintiff who is not a participant in the Medicare program and thus does not have access to the administrative appeals process can be barred by Section 405(h) from bringing a cause of action challenging administrative procedural irregularities under the Medicare Act. Nor has this Court ever held that a Plaintiff who had no access to the administrative appeals process has to affirmatively prove there are no adequate proxies who can bring similar claims or causes of action.

Regenative readily acknowledges that at least one provider called a Medicare contractor to inquire about reimbursement status of Regenative's products. That is a far cry from going through the five levels of Medicare appeals and raising Regenative's causes of action through each level. Similarly, several providers have pursued administrative appeals with respect to reimbursement decisions on Regenative's products, but none of those providers are or even can raise Regenative's causes of action to redress the specific harms to Regenative.

In *Illinois Council*, this Court was careful to ensure that judicial actions would not be barred where the bar effectively leads to no judicial review at all. *Illinois Council*, 529 U.S. at 17, 19. That is premised on the fundamental principle that judicial review of agency action against an aggrieved person will not be cut off. *Michigan Academy,* 476 U.S. at 670. But that is exactly what is happening here where Regenative itself has no access to the administrative appeals process. The plaintiff in *Illinois Council* was

an association of nursing homes, each of whom was a provider participant in the Medicare program and thus had access to the administrative appeal process. *Illinois Council,* 529 U.S. at 5.

It is of no consolation to Regenative that some providers might initiate the administrative appeals process, or that one or more providers might even see that process through the many layers of appeal to get to judicial review of the administrative decisions on their individual claims. At that point, the judicial review is limited to the administrative record, in which Regenative had no involvement in developing. Regenative's causes of action never get heard.

The interpretation of the D.C. Circuit effectively reads the phrase "to recover on any claim arising under" completely out of the statute. Under the interpretation of the D.C. Circuit, Section 405(h) would bar essentially any lawsuit that potentially has implications for any reimbursement decision, regardless of who is bringing the lawsuit or what the nature of the causes of action are. But the language of the statute is not so broad as to bar any judicial action under the Medicare Act. Instead, it is limited to judicial actions "to recover on any claim". 42 U.S.C. §405(h). Those words must mean something in limiting the scope of judicial actions foreclosed. The language of the statute itself is not as capacious as the court of appeals suggests.

II. The District of Columbia Circuit's Decision regarding Mootness Conflicts with This Court's Precedent.

"Voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice unless it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Hum. Res.*, 532 U.S. 598, 609 (2001) quoting *Friends of Earther, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000).

As acknowledged by the D.C. Circuit, here Regenative is not only alleging that the wrongful behavior could be expected to recur. Regenative has alleged that the wrongful behavior never stopped. Pet. App. 16a ("Appellant protests that Medicare contractors continue to apply the rescinded policy in full force, …, claiming that the Government merely 'faux-ceas[ed]' the policy").

Regenative's action asserts that the Government improperly implemented a change in coverage determination policy without required Notice and Comment, and that change in policy has never actually changed. What Regenative seeks is for that policy to be ordered to be vacated. At that point, if CMS wants to implement a National Coverage Determination (NCD), it can do so through the statutorily prescribed Notice and Comment procedure. Absent this lawsuit, Regenative has no mechanism to redress that wrong or to get any

judicial review of its causes of action to correct that wrongful action by the Government.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully Submitted,

PATRICK GALLAGHER
Counsel of Record
PC GALLAGHER LAW P.A.
13860 Wellington Trace, Ste. 38-103
Wellington, Florida 33414
(312) 498-5411
patrick@pcgallagher.com