No. 23-1326

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

REPLY BRIEF FOR THE PETITIONER

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I. The Decision of the Court of Appeals Conflicts with this Court's Decisions in *Illinois Council* and *Michigan Academy*.

The decision of the court of appeals for the D.C. Circuit directly conflicts with this Court's decision in *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000) (hereinafter "*Illinois Council*"). In *Illinois Council,* this Court held (in a narrow 5-4 decision) that 42 U.S.C. § 405(h) in the context of Medicare did not prevent judicial actions where the channeling mechanism would mean no judicial review at all of the asserted action. *Illinois Council*, 529 U.S. at 17-18. In this case, applying the Section 405(h) bar will mean there will be no judicial review at all of Regenative's causes of action, which is in direct conflict with this Court's decision in *Illinois Council*. Regenative is not a participant in the Medicare program, and while directly impacted by Medicare, Regenative does not have any access to the Medicare administrative appeals process.

In its opposition, the Government conveniently ignores the portion of Section 405(h) that limits the channeling mechanism to a judicial action to "recover on any claim." Instead, the Government asserts that under the Medicare statute a litigant cannot obtain judicial review of claims "arising under" Medicare unless first presented to the agency. *See* Opp. Br. At 12. Regenative is not seeking to "recover on any

claim" and indeed Regenative cannot recover on any claim under the Medicare statute—Regenative is not a provider or beneficiary under Medicare.

The Government's argument conflicts with the explicit language of the statute, and with this Court's decisions in *Illinois Council* and *Michigan Academy*. *See Illinois Council*, 529 U.S. at 19 (The channeling bar does not apply "where application of §405(h) would not simply channel review through the agency, but would mean no review at all"); *Bowen v. Michigan Academy of Family Physicians*, 476 U.S 667, 680 ("we will not indulge the government's assumption that Congress … intended no review at all of substantive statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program."). Under *Michigan Academy*, this Court "ordinarily presume[s] that Congress intends the executive to obey its statutory commands, and accordingly, that it expects courts to grant relief when an executive agency violates such a command." 476 U.S. at 681. Regenative's complaint in this case seeks to hold the Government accountable to follow required notice and comment procedures required under the Administrative Procedures Act and the Medicare statute. *See Azar v. Allina Health Servs.*, 587 U.S. 566 (2019). But Regenative, or any other non-Medicare participant, can only get to the point of arguing its cause of action for notice-and-comment, once this Court addresses a threshold question whether Regenative has any right to judicial review at all.

Under *Illinois Council* and *Michigan Academy*,

the Section 405(h) bar certainly cannot be used against Regenative, who has no access to the Medicare administrative appeals process at all. Thus, applying the 405(h) "channeling" mechanism against Regenative is a complete bar to judicial review of Regenative's causes of action.

This is an important question because Regenative and other non-Medicare participants, including manufacturers, distributors, and related service providers, cannot be heard at all without direct access to judicial review. Without this Court further addressing and settling the question of applicability of Section 405(h) to individuals and entities who themselves have no access to the Medicare appeals process, CMS is likely to continue to defy requirements for notice and comment with impunity, without threat of realistic repercussions.

While the Government cites a litany of sections of the Medicare statute, the Public Health Service Act, the Code of Federal Regulations, and various guidance from CMS and FDA, all of those citations are irrelevant to the issue currently before the Court here. The issue presented here is Regenative's ability to maintain a cause of action to hold CMS accountable to follow statutorily required notice-and-comment procedures. Regenative welcomes the opportunity to eventually address all of those citations to statues, regulations, and guidance. If Regenative had been given an opportunity for notice and comment before CMS altered its policies, Regenative could have already done that. But none of those citations are at issue here—what is at issue is the Court of Appeals

depriving Regenative of the right to judicial review to have the opportunity for notice and comment in the first place.

II. This Court has not decided a case under Section 405(h) where the Plaintiff does not participate in the Medicare program and thus does not have access to the Medicare administrative appeals process.

Instead of applying a straightforward application of *Illinois Council*, the decision of the Court of Appeals assumes that some unnamed proxies could potentially bring similar claims, and on that basis applies the Section 405(h) bar against Regenative. This Court has never decided a case applying Section 405(h) or *Illinois Council* where the Plaintiff had no access to the Medicare administrative appeals process.

The cases from this Court cited by the Government in opposition to the petition for certiorari all concern cases where the plaintiffs had access to the administrative appeals process.

In *Weinberger v. Salfi*, this Court held that Section 405(h) barred judicial action on behalf of unnamed class members who as social security beneficiaries may not have exhausted administrative remedies. 422 U.S. 749, 763 (1975). Those unnamed class members whose claims were barred all would have had access to the administrative appeals process. *Id.*

In *Heckler v. Ringer*, individual Medicare claimants brought a judicial action challenging the lawfulness of the agency's determination not to provide Medicare reimbursement to those who had undergone a particular medical operation. 466 U.S. 602, 605 (1984). Each of those individuals were participants in Medicare and had access to bring administrative appeals challenges. See *id.* at 614-16, 621-23. The Court held that with respect to those Medicare participants, Section 405(h) barred judicial action where "exhaustion of administrative remedies is in no sense futile for these respondents." *Id.* at 619.

In *Michigan Academy*, this Court held that Section 405(h) did not bar judicial action by an association of family physicians and individual doctors under the Medicare statute. 476 U.S. at 668. Even though the association members had access to the Medicare administrative appeals process, this Court held that those claims were not barred on the basis 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*. at 681.

In *Illinois Council*, this Court determined that an action by an association of nursing homes was barred by Section 405(h) where "The Council's members remain free, …, after following the special review route that the statutes prescribe, to contest in court the lawfulness of any regulation or statute upon which an agency determination depends." 529 U.S. at 23. The Court held that for purposes of Medicare Section 405(h) does not apply where application

"would not simply channel review through the agency, but would mean no review at all." *Id*. at 19.

Each of these cases interpreting the scope of Section 405(h) involved a beneficiary or provider (or association of providers) who had access to the administrative appeals process. After *Illinois Council*, Section 405(h) does not bar judicial actions that would mean no judicial review at all of the action. *Id*. at 19.

This Court has not addressed the question of how Section 405(h) and the precedent in *Illinois Council* applies for a Plaintiff who is not a Medicare participant, and thus has no access to the administrative appeals process.

Under Illinois Council, this Court made clear that Section 405(h) is not a litigation bar where application would preclude judicial review of a party's causes of action. This Court has not yet addressed a situation, such as here, where a medical products manufacturer with no access to the Medicare administrative appeals process brings a judicial action challenging the agency's failure to obey basic statutory commands (notice and comment).

Applying a Section 405(h) bar against Regenative in this case means no judicial review at all of Regenative's causes of action. Instead of applying this Court's precedent from *Illinois Council*, the Court of Appeals has injected the concept of "proxies" who potentially could bring a comparable claim instead of Regenative. But that concept has no basis in the

decisions of this Court, and conflicts with this Court's decisions in *Illinois Council* and *Michigan Academy*.

III. The lower federal courts have inconsistently applied *Illinois Council*, especially with respect to Plaintiffs who do not directly have access to the Medicare administrative appeals process.

Both among Circuits and within Circuits, *Illinois Council* has been applied inconsistently in terms of the Section 405(h) litigation bar, especially with respect to Plaintiffs who do not themselves directly have access to the administrative appeals process.

The Government cites to certain decisions holding that Section 405(h) barred suits based on the availability of potential "proxies". *See National Athletic Trainers' Ass'n v. HHS*, 455 F.3d 500 (5th Cir. 2006) (lawsuit barred by Section 405(h) where Medicare providers could potentially challenge rule); *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 983-84 (9th Cir. 2020) (Section 405(h) bar applies where another party can bring a claim through administrative appeals and is sufficiently incentivized to do so); *Retina Group of New England, P.C. v. Dynasty Healthcare, LLC*, 72 F.4th 488, 497 (2d Cir. 2023) (holding action barred under Section 405(h) because others could potentially have brought

similar claims through administrative appeals process).

But other decisions from lower Courts take drastically different approaches to the *Illinois Council* decision. *See Buchanan v. Apfel*, 249 F.3d 485, 490 (6th Cir. 2001) (holding Section 405(h) does not bar action by attorney under Section 405(h) because "Congress never contemplated a situation where someone other than a party pursuing entitlement benefits would seek review of a colorable claim.") *Furlong v. Shalala*, 238 F.3d 227, 236 (2d Cir. 2001) (holding that under the analysis of *Michigan Academy* and *Illinois Council* claims are not barred by Section 405(h) for physicians whose access to administrative appeals are limited because they have not received assignment of Medicare beneficiary claims); *Binder & Binder PC v. Barnhart*, 481 F.3d 141 (2d Cir. 2007) (holding judicial action not barred by Section 405(h) where plaintiff law firm would otherwise be unable to obtain any judicial review at all).

District Court decisions are also instructive here for the inconsistent application of Section 405(h) and *Illinois Council*, especially where the Government is the Defendant and electing not to appeal those decisions. In *Akebia Therapeutics, Inc. v. Becerra*, the District of Massachusetts held that a pharmaceutical company's claims were not barred by Section 405(h) because "it is in a category of entities, pharmaceutical companies, that are seemingly wholly excluded from the Part D administrative review process. 548 F. Supp. 3d 274, 286-87 (D. Mass. 2021). In *Baxter*

Healthcare Corp. v. Weeks, The District Court for the District of Columbia held that a manufacturer's action was not barred by Section 405(h) where the plaintiff was not suing on behalf of anyone who could seek judicial review and plaintiff was not required to recruit a proxy for an administrative process. 643 F. Supp. 2d 111, 116 (D.D.C. 2009).

Each of these decisions are demonstarrtive for this Court of the inconsistent application of *Illinois Council* by lower courts. And with respect to these two District Court decisions, the Government elected not to appeal, which creates a selection bias of sorts for cases at the level of the Circuit Courts of Appeals.

Contrary to the suggestion of the Government, it is no consolation to Regenative that some Medicare participants might have pursued "claims comparable" to those pursued by Regenative. *See* Opp. Br. At 13-14. While they might be comparable, those are not Regenative's claims. In a footnote, the Government cites to cases other entities have filed against CMS. But the Government does not even try to characterize those cases as similar or comparable.

To the extent any Medicare provider chooses to pursue administrative appeals on claims related to Regenative's products or arguably comparable HCT/P products, those administrative appeals are limited to specific claims for reimbursement, limited to the administrative record those providers choose to introduce, and limited to the extent those claimants

choose to settle rather than fully pursue any such claims.

The Government also does not mention in its opposition comparable cases to those cited in footnote 2 where the Government has taken the position that causes of action "comparable" to Regenative's were not preserved. In *Greiner Orthopedics, LLC v. Becerra*, a Medicare provider went through the administrative appeals process, a product manufacturer has tried to join at the District Court stage, but with respect to the "Secret Policy" arguments similar to those Regenative has raised, the Government has taken the position that those arguments have not been preserved through the administrative appeals process. *See* D.I. 30 at 37-38, *Greiner Orthopedics, LLC v. Becerra*, No. 23-cv-01047 (D.D.C. Jan. 19, 2024).

In this case Regenative has its own causes of action seeking to hold CMS accountable to obey statutory commands to follow basic notice and comment procedures. Regenative's causes of action cannot be vindicated by another third party who might pursue similar claims, or who might preserve those claims through the multiple levels of administrative appeal, or who might find a settlement suitable to them (but not to Regenative). Regenative's only opportunity for judicial review of its causes of action are for this Court to ensure that Regenative can pursue its own lawsuit and not be dependent on others who may or may not pursue Regenative's interests.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully Submitted,

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