IN THE SUPREME COURT OF THE UNITED STATES

No. 24A-_____

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

v.

XAVIER BECERRA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
RESPONDENTS

APPLICATION FOR AN EXTENSION OF TIME
WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TO: John G. Roberts, Jr., Chief Justice for the United States Court of Appeals for the District of Columbia:

Pursuant to Rules 13.5 and 30.3 of the Rules of this Court, Applicant Row 1 Inc. d/b/a Regenative Labs, respectfully requests a 30-day extension of time, to and including June 16, 2024, within which to file a petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case. The court of appeals entered its judgment on February 16, 2024. Therefore, unless extended, the time within which to file a petition for a writ of certiorari will expire on May 16, 2024. The jurisdiction of this Court would be invoked under 28 U.S.C. 1254(1). Copies of the opinion of the court of appeals, which is reported at 92 F.4th 1138 is attached.

1. This case concerns the Medicare program channeling requirement under 42 U.S.C. 405(h), and whether a medical products

manufacturer who is not the procedural challenge to Centers for Medicare and Medicaid Services ("CMS") for adopting new rules and regulations governing whether a manufacturer of medical products who has no opportunity to participate in any Medicare appeals is foreclosed from availability of subject matter jurisdiction for a medical products manufacturer to

2. In February 2022, CMS issued two technical direction letters (TDLs) to each of the Medicare Administrative Coordinators (MACs), in which CMS directed that claims for certain Human Cellular and Tissue-Based Products (HCT/Ps) be denied. The second TDL explicitly referenced REgenative's products as one of those for which all claims should be denied. This was a drastic change in policy as CMS had been regularly reimbursing for these HCT/Ps. Not only did CMS not go through required and standard Notice and Comment procedures for that change, but CMS specifically directed the MACs not to disclose this change in direction outside of their organizations. Regenative Labs learned of the TDLS in the context of the underlying lawsuit and seeks to challenge CMS's failure to go through Notice and Comment.

a. The District Court held, and the Appellate Court affirmed, that the courts did not have subject matter jurisdiction based on the channeling requirement under 42 U.S.C. 405(h), which requires actions "to recover on any claim" under the Medicare statute to go through the five-layered Medicare appeals process.

b. Regenative, however, has no access to that Medicare appeals process because it is not a provider or beneficiary. Without having access to the courts, Regenative is thus deprived of any ability to challenge the failures of CMS to challenge the failure of CMS to follow basic administrative procedural

requirements.

3. Applicant has only recently retained undersigned counsel with respect to evaluating whether to file a petition for a writ of certiorari in this case. The additional time sought in this application is needed for further consultation to assess the legal and practical impact of the court's ruling. If Applicant decides to move forward with a petition for certiorari, additional time is also needed to prepare the petition for printing and filing.

Respectfully submitted,

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