

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*

**MOTION FOR LEAVE TO FILE BRIEF OF THE
GREATER PENSACOLA CHAMBER OF COMMERCE
AS AMICUS CURIAE IN SUPPORT OF
PETITIONER'S WRIT OF CERTIORARI**

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

1. On July 17, 2024, the undersigned filed her Brief of Greater Pensacola Area
Chamber of Commerce as Amicus Curiae in Support of Petitioner's Writ of Certiorari.

2. On July 29, 2024, the Clerk for the U.S. Supreme Court's office informed the
undersigned that both parties were not given timely notice to file and that approval to file
without the notice required must be granted by Counsel for both the Petitioner and the
Respondents.

3. The undersigned contacted Patrick C. Gallagher, Esq., Counsel for Petitioner, and
Counsel for the Respondents, Elizabeth B. Prelogar, Esq. on July 29, 2024. Mr. Gallagher
stated that he had no objection to the Brief being submitted, however, no response has been
received from Ms. Prelogar.

4. Both Counsels for the Petitioner and the Respondents received the brief following the filing on July 17, 2024, and have had sufficient notice of the same.

WHEREFORE, Autumn Beck Blackledge, Esq., Counsel for Amicus Curiae, hereby requests that this Motion for Leave to File Brief of The Greater Pensacola Area Chamber of Commerce as Amicus Curiae in Support of Petitioner's Writ of Certiorari be granted.

Respectfully Submitted,

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INTEREST OF AMICUS CURIAE¹

The Greater Pensacola Chamber of Commerce submits this amicus curiae brief in support of Row 1 Inc. d/b/a Regenerative Labs. The Greater Pensacola Chamber of Commerce, established in 1889, is dedicated to promoting the region's quality of life and fostering economic growth through community engagement and business support. The Chamber represents a diverse array of over 1,200 businesses and organizations, encompassing business executives, entrepreneurs, civic leaders, and educators. Its initiatives include various programs and events designed to help members build strategic relationships and enhance their business prospects. With a focus on member engagement, armed services, and government affairs, the Chamber plays a pivotal role in the economic and civic vitality of the Pensacola region which inhabits over 327,000 residents. The Chamber represents the interests of businesses in the Pensacola area, advocating for economic development, business-friendly policies, and job creation. The outcome of this case holds significant implications for the local economy, particularly in fostering innovation and growth in the biomedical sector.

¹ Under Rule 37.6 of the Rules of this Court, amicus state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus or their counsel made a monetary contribution to its preparation or submission.

INTRODUCTION AND SUMMARY OF ARGUMENT

Regenerative Labs plays a crucial role in the economic development of Pensacola and the surrounding regions. Its innovative work in the biomedical field not only advances medical technology but also creates high-quality jobs and stimulates local economic growth. The Greater Pensacola Chamber of Commerce believes that the decision of the lower courts, if left unchallenged, will adversely affect the ability of Regenerative Labs to operate effectively, thereby stifling economic progress and innovation in our community.

ARGUMENT

1. Regenerative Labs should be afforded standing to determine whether or not policies adopted by the Center for Medicare and Medicaid Services impede their business because the economic impact on the Greater Pensacola Area is impacted.

Regenerative Labs has established itself as a leading innovator in the biomedical sector, particularly in the development of human amniotic and placental tissue products. The company's operations contribute significantly to the local economy by creating jobs, fostering local business growth, and attracting investment to the region. It has been operating in the Pensacola area since its incorporation in December of 2018. The company is a manufacturer of human cell and tissue products and also provides tissue banking solutions.

The human cell and tissue manufacturing industry is experiencing significant growth, driven by advancements in bioprinting, tissue engineering, and stem cell technologies.

For example, the 3D Bioprinted Human Tissue Market was valued at approximately \$2.3 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 8.4% from 2024 to 2032. This growth is fueled by investments in biotechnology research and development, with applications ranging from drug discovery to regenerative medicine. *See Global 3D Bioprinted Human Tissue Market Size, Share, Trends: By Tissue Type: Skin, Cartilage, Liver, Bone, Heart, Others; By Technology: Inkjet-based*

Bioprinting, Extrusion-based Bioprinting, Laser-assisted Bioprinting, Magnetic Bioprinting; By Applications: Drug Discovery, Others; By End User; Regional Analysis; Supplier Landscape; 2024-2032

As it relates to the Stem Cell Manufacturing Market, this market is projected to grow at a CAGR of 12.9% over the forecast period, driven by technological advancements and increased public-private investments. Stem cell therapies are increasingly being used to treat various diseases, and significant growth is expected in the Asia-Pacific region due to the adoption of innovative technologies. See Mordor Intelligence; *Stem Cell Manufacturing Market Size & Share Analysis - Growth Trends & Forecasts(2024-2029)*.

When it comes to Cell and Gene Therapies (CGT), the CGT market is also on a growth trajectory, with significant synergies between orphan drug designations and CGT economic incentives. This sector is projected to benefit from increased collaboration and licensing agreements, which have shown resilience despite macroeconomic challenges. The market is expected to see a resurgence in funding and investment activity as interest rates stabilize See *2024's Market Outlook For Cell & Gene Therapies* By Justin Culbertson and Adam Lohr, RSM US LLP Cell and Gene, February 9, 2024.

Overall, the human cell and tissue manufacturing industry is expanding rapidly, supported by technological innovations and growing investments in research and development. These advancements promise to transform healthcare with

new regenerative medicine and therapeutic solutions. These advances in health care are necessary for our country to remain globally competitive, but also critical for our state and local communities and their economic futures.

Regenerative Labs has generated numerous high-skilled jobs in the Pensacola area, employing local talent in various capacities including research, development, manufacturing, and administrative roles. These are the types of jobs that will help retain young talent in our community, such as graduates from the University of West Florida, Pensacola State College, George Stone Technical College, and Locklin Technical College. The average salary for a biomedical engineer in the United States was just under \$100,000, illustrating the high-quality job opportunities provided by Regenerative Labs. For a community with a median income of only \$61,924², attracting high wage, high tech jobs can mean a better quality of life for all its citizens. High wage technical jobs such as those created are critical to the Pensacola economy and future.

For example, the presence of Regenerative Labs in the Greater Pensacola area has encouraged the growth of ancillary businesses including suppliers, logistics providers, and service industries, further bolstering the local economy. The company's operations bring in money from outside our region, expanding the local tax base. This economic

² Neilsberg Research, Escambia County, Florida Median Household Income by Age updated January 10, 2024 though the median income for those under 25 is significantly lower at only \$37,136 per year.

multiplier effect underscores the significance of maintaining such innovative companies within our community.

One of the most significant impacts has been that the company's innovative work and success have attracted significant investment to the area, enhancing the region's reputation as a hub for biomedical innovation. Diversifying our local economy is a focus of the Greater Pensacola Chamber of Commerce and having Regenerative Labs in our community helps with that mission. Investors are drawn to regions with a robust and innovative biomedical sector, as evidenced by the \$2.8 billion in venture capital invested in U.S. biomedical companies in 2022 alone (National Venture Capital Association, 2022).

Additionally, the recent ruling in *Loper Bright Enterprises v. Raimondo* 603 U.S. __ 2024³ which overturned *Chevron USA v. National Resources Defense Council*, 467 U.S. 837 (1984) and the federal judiciaries' forty-year old practice of deferring to agencies' reasonable interpretations of ambiguous federal law, underscores the necessity for judicial oversight in administrative decision-making. This shift emphasizes that courts should not automatically defer to agency interpretations of ambiguous statutory language. Consequently, Regenerative Labs should be afforded standing to challenge policies adopted by the Center for Medicare and Medicaid Services (CMS) that impede their business

³ The Court's decision was also issued in the Loper's sister case, *Relentless, Inc. v. Dep't of Commerce*, No. 22–1219, 603 U.S. __ 2024

operations. This is particularly vital given the significant economic impact on the Greater Pensacola Area, where Regenerative Labs plays a crucial role in job creation and local economic growth. Ensuring robust judicial review can prevent arbitrary administrative actions that stifle innovation and economic progress in the biomedical sector.

2. Thousands in the Greater Pensacola area are enrolled in Medicaid and/or Medicare and the decision in this matter directly impacts their healthcare choices and costs.

Escambia and Santa Rosa counties have substantial enrollment in Medicaid and Medicare. In 2022, Escambia had 87,328 Medicaid enrollees out of a population of 327,595, and Santa Rosa had 24,633 enrollees out of 171,851. In 2023, Medicare enrollment in Escambia was 73,910, and in Santa Rosa, it was 40,363. These figures highlight the critical role of healthcare services and the need for innovative medical solutions provided by companies like Regenerative Labs to support the local population. The high enrollment rates in Medicaid and Medicare indicate a significant portion of the population relies on these programs for their healthcare needs. Given the aging population and the increasing prevalence of chronic conditions, the demand for advanced medical treatments and technologies is growing. Regenerative Labs' work in developing human amniotic and placental tissue products directly addresses these needs by offering innovative treatments that can improve patient outcomes and reduce healthcare costs.

Moreover, the local hospitals and healthcare providers, including Ascension Sacred Heart, Baptist Health Care, and HCA Florida West Hospital, benefit from the presence of cutting-edge biomedical companies. These institutions can integrate the latest advancements into their care protocols, enhancing the quality of care for residents. By fostering a robust healthcare ecosystem, Regenerative Labs not only contributes to better health outcomes but also helps in retaining and attracting healthcare professionals to the area, addressing another critical need in the community. Additionally, Regenerative Labs is positively impacting communities everywhere with its state of the art health care innovation.

The economic impact of maintaining a healthy population cannot be overstated, not only in the Greater Pensacola Area, but in all communities. Healthier individuals are more productive, which contributes to the overall economic stability and growth of the region. As such, supporting companies like Regenerative Labs aligns with broader economic development goals, ensuring that the local population has access to state-of-the-art medical care, which in turn supports a more vibrant and resilient community.

3. The dismissal of the lower court should be reversed because a company should be afforded the opportunity to challenge procedural irregularities and policies that directly affect its operations.

The decision of the lower courts to dismiss Regenerative Labs' case for lack of subject matter

jurisdiction under 42 U.S.C. § 405(h) significantly hampers the company's ability to challenge procedural irregularities and policies that affect its operations. Not only does it stifle innovation but also does economic harm to the communities where the businesses are located.

By preventing Regenerative Labs from seeking judicial review of CMS's policy changes, the decision stifles innovation and impedes the development of new medical technologies that benefit patients and the healthcare industry. This was seen in the case of *StimLabs, LLC v. Becerra*, where CMS's policy changes broadly denied claims for manipulated amniotic and/or placental tissue biologics, significantly impacting the businesses involved *StimLabs, LLC v. Becerra*, 636 F. Supp. 3d 165 (D.D.C. 2022). The court's decision underscored the adverse impact of CMS's unwritten policy on the ability of companies to innovate and bring new medical technologies to market.

The inability to challenge adverse policies directly impacts Regenerative Labs' business operations, potentially leading to job losses and reduced economic activity in the Pensacola area. Losing a company like Regenerative Labs would be a great blow to our community. The negative economic consequences are not hypothetical; in the StimLabs case, the plaintiffs provided evidence that the loss of Medicare coverage for their products would result in a significant loss of revenue, potentially threatening the viability of their business *See id.*

Upholding the lower court's decision sets a dangerous precedent that may deter other businesses

from investing in innovative ventures due to the increased regulatory uncertainty and limited recourse for challenging administrative actions. Similar issues were addressed when CMS rescinded a previous mandate broadly denying claims for certain birth tissue biologics following clarifications from the FDA See e.g. *CMS Pulls Back from Denying Claims Related to Birth Tissues*, American Association of Tissue Banks, Mar. 31, 2022). The willingness of CMS to revise its policies in response to stakeholder input highlights the importance of allowing judicial review to ensure administrative accountability.

Again, The Supreme Court's recent reversal of *Chevron* deference highlights the critical importance of judicial review in maintaining fair and accountable administrative processes. By limiting the automatic deference previously granted to agencies, the ruling strengthens the argument that companies like Regenerative Labs must have the opportunity to challenge procedural irregularities and policies that directly affect their operations. The decision of the lower courts to dismiss Regenerative Labs' case hampers their ability to innovate and economically benefit the Pensacola community. Judicial oversight is essential to prevent undue regulatory burdens that can lead to job losses and reduced economic activity, as evidenced by the *StimLabs LLC v. Becerra* case.

4. Judicial review of Administrative Policies is critical to the smooth operation of businesses by ensuring fairness and accountability.

Judicial review of administrative actions is essential to ensure that agencies like CMS adhere to statutory requirements and procedural fairness. In

this case, CMS's policy changes regarding the denial of payments for amniotic and placental tissue biologics were implemented without the necessary notice and comment period, undermining the principles of transparency and accountability.

Allowing Regenerative Labs to seek judicial review ensures that CMS's actions are scrutinized for compliance with statutory and procedural requirements, promoting fairness and accountability. This principle is supported by the ruling in ___, where the Supreme Court emphasized the necessity of judicial review to prevent the agency from acting without proper oversight *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000).

Judicial review protects the economic interests of businesses like Regenerative Labs by providing a mechanism to challenge potentially harmful administrative decisions, thereby fostering a business-friendly environment conducive to economic growth. The need for judicial review is underscored by the fact that procedural safeguards, such as notice-and-comment rulemaking, are designed to prevent arbitrary and capricious actions by administrative agencies (Administrative Procedure Act, 5 U.S.C. §§ 551-559).

Ensuring that companies like Regenerative Labs can seek judicial review encourages continued investment in innovative biomedical research. The uncertainty created by the lack of judicial review can stifle innovation, as companies may be hesitant to invest in new technologies if they cannot challenge adverse administrative decisions. This was clearly demonstrated in the *StimLabs* case, where the

company argued that the CMS policy changes threatened its ability to continue developing innovative medical products. *Id.* *StimLabs, LLC v. Becerra*, 636 F. Supp. 3d 165 (D.D.C. 2022)).

Lastly, the Supreme Court's recent ruling on striking the “Chevron deference” reinforces the principle that judicial review is essential to ensuring fairness and accountability in administrative actions. By curtailing automatic judicial deference to agency interpretations, the ruling mandates that courts more rigorously scrutinize agency decisions for compliance with statutory and procedural requirements. This change is crucial for businesses like Regenerative Labs, which rely on transparent and fair administrative processes to challenge adverse policies. The ability to seek judicial review ensures that CMS’s actions are subject to proper oversight, promoting a business-friendly environment conducive to economic growth and innovation.

5. Support for biomedical companies from Chambers of Commerce nationally is not unique.

It is important to note that the support for laboratories and biomedical companies by Chambers of Commerce is not unprecedented. The U.S. Chamber of Commerce has filed amicus briefs in cases involving significant regulatory issues that impact laboratories and biomedical companies. For instance, the U.S. Chamber supported Laboratory Corporation of America Holdings (LabCorp) in litigation that had considerable implications for the regulatory environment of laboratory operations. This

involvement underscores a broader recognition of the importance of judicial oversight to ensure that regulatory practices do not unduly stifle innovation or impose unjust burdens on businesses.

These cases illustrate the critical role that judicial review plays in maintaining a balanced regulatory environment that fosters innovation and economic growth. They further highlight the necessity for courts to provide a venue for challenging potentially harmful administrative actions, ensuring that businesses can continue to contribute positively to the economy and public health. The limitation of the "Chevron deference" by the US Supreme Court strengthens the need for judicial review of administrative policies, a point underscored by Chambers of Commerce in supporting biomedical companies. This shift highlights the broader recognition of the necessity for courts to play a pivotal role in maintaining a balanced regulatory environment. Judicial oversight ensures that regulatory practices do not unduly stifle innovation or impose unjust burdens on businesses. For Regenerative Labs, this means having a viable pathway to challenge harmful CMS policies, thereby protecting their ability to contribute positively to the economy and public health through continued biomedical innovation.

CONCLUSION

For the foregoing reasons, The Greater Pensacola Chamber of Commerce respectfully urges the Court to grant the petition for a writ of certiorari and reverse the decision of the United States Court of Appeals for the District of Columbia Circuit. Ensuring that Regenerative Labs can seek judicial review of CMS's policy changes is crucial for promoting innovation, economic development, and fairness in the administrative process.

Respectfully submitted,

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