

Personalized Health Association Announces National Initiative to Modernize Stem Cell & Regenerative Medicine Policy

Calls for Updated 21 C.F.R. §1271.10(a) Framework

WASHINGTON DC, DC, UNITED STATES, December 12, 2025 /EINPresswire.com/ -- The [Personalized Health Association](#) (PHA), the nation's leading advocacy organization for regenerative and precision medicine, today announced a national initiative to modernize federal policy governing adult stem cell and PRP therapies. This initiative builds on the recently filed Citizen Petition seeking targeted updates to 21 C.F.R. §1271.10(a) to establish a clear, cGMP-based regulatory pathway allowing certain adult stem cell products to be regulated as 361 HCT/Ps when manufactured in accredited, FDA-registered facilities.

The policy modernization effort is designed to expand safe patient access, strengthen physician-directed care, and eliminate longstanding regulatory ambiguity, while maintaining rigorous safety and quality standards across the regenerative medicine field.

Lee Rosebush, Esq., lead strategic advisor to PHA and co-author of the Citizen Petition, said, "The proposed update to 1271.10(a) presents a practical, science-centered pathway that enhances patient access while maintaining the strongest safety safeguards. Allowing certain adult stem cell products to qualify as 361 HCT/Ps when manufactured in cGMP-compliant, accredited facilities brings regulatory clarity to clinicians, patients, and innovators. This modernization strengthens safety, empowers physician-directed care, and aligns federal oversight with the realities of modern regenerative medicine. PHA is leading this effort because it's time the regulatory framework caught up with the science."

Jimmy St. Louis, president of PHA, said, "This can be a defining moment for regenerative medicine. Patients and clinicians should expect clarity on a regulatory pathway that allows them to continue to advance innovative healthcare, allowing them to meet previously unmet needs. In this area of medicine, clinics are often burdened with outdated rules that do not reflect the strength, safety, or maturity of today's regenerative therapies. The initiative PHA is leading—supported by Lee's unmatched regulatory expertise—creates a clear, responsible, and forward-looking pathway. Our commitment is simple: educate, protect patients, define and elevate standards, and expand access to safe, individualized regenerative care."

PHA's national initiative focuses on:

- advancing modernization of 21 C.F.R. §1271.10(a);
- establishing a national 361 HCT/P pathway for certain adult stem cell products manufactured under cGMP conditions;
- encouraging accredited facility standards modeled after successful state frameworks;
- protecting physician directed regenerative protocols such as PRP, MSC therapies, and orthobiologics;
- supporting 503A compounding and peptide therapy access as essential to individualized regenerative care;
- elevating safety, transparency, and manufacturing integrity across the field; and
- creating a consistent, science-based regulatory environment that deters bad actors while empowering ethical innovators.

Bill Moses, founder of PHA, said, "Modernizing the 1271 framework is essential to expanding safe patient access and bringing federal policy in line with today's regenerative science."

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