# What To Expect For Stem Cell Regulation Under Trump Admin

By **Dominick DiSabatino and Audrey Mercer** (March 25, 2025)

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Where does the right to use one's own stem cells end and the federal government's right to regulate them begin? The question sounds rhetorical, but soon, it might be answerable.

Those in the industry know that innovation in the stem cell field has progressed rapidly over the last 10 years or so, and a lighter regulatory touch by the U.S. Food and Drug Administration is poised to accelerate that growth.

The FDA currently regulates stem cells as human cells, tissues, and cellular and tissue-based products, or HCT/Ps, through a complex regulatory structure, rooted in a broad grant of authority to regulate under the Public Health Service Act Sections 351 and 361.

However, the new administration's push for deregulation, current post-Chevron legal landscape, and momentum from key political and industry players to facilitate stem cell innovation may create an opportune backdrop for a significant reduction in the FDA's regulatory framework for HCT/Ps and, importantly, greater accessibility for the general public.

**Current Regulatory Framework and Court Interpretations**

Due to the unique nature of HCT/Ps, the FDA regulates them based on a tiered, risk-based approach.[1] The default status of HCT/Ps is "drugs," subject to the full scope of the FDA's drug and biologic regulations, including Title 21 of the Code of Federal Regulations, Section 1271.[2]

However, if an HCT/P meets four requirements,[3] it will be regulated solely under Section 361 of the PHSA[4] and will thus be exempt from premarket review and approval — only required to comply with the FDA's registration/listing requirements and the requirements outlined in the FDA's HCT/P-specific regulations. Two of the more commonly contested requirements are minimal manipulation and homologous use.

"Minimal manipulation" is defined differently for structural tissue versus cells and nonstructural tissues, but essentially refers to a process by which the original characteristics of the tissue and/or cell remain unchanged.[5]

As explained by the FDA, the determination of whether an HCT/P is minimally manipulated is based on the effect of manufacturing on the original relevant characteristics of the HCT/P as the HCT/P exists in the donor, and not based on the intended use of the HCT/P in the recipient.[6]

"Homologous use," on the other hand, is based on intended use — and means that the cell or tissue performs the same basic function in the recipient as in the donor.[7] As with any other assessment of intended use, the FDA will look to a broad body of evidence, including the labeling, advertising and any other indications of the manufacturer's objective intent, to determine whether a product is intended solely for homologous use.[8]

Further, an HCT/P establishment is eligible for complete exemption from FDA regulation if it meets one of five regulatory exemptions outlined at Title 21 of the Code of Federal Regulations, Section 1271.15, one of which is an exemption for HCT/Ps that are removed from an individual and implanted into the same individual during the same surgical procedure, where the HCT/P is not significantly processed.[9]

Meeting any one of these exemptions means that a company can bring its product to market for a fraction of the resources it would have had to spend if its HCT/P were regulated as a new drug.

For this reason, federal courts have been called upon to interpret the exemption pathway, specifically the same surgical procedure exemption.

The U.S. Courts of Appeals for the Ninth Circuit and Eleventh Circuit have both narrowly construed the same surgical procedure exemption procedure, each holding that stem cell treatments that chemically isolate stromal vascular fraction, or SVF, from extracted tissue and insert the resulting SVF back into the patient fail to meet the exemption — and are, therefore, new drugs requiring full compliance with FDA regulations — because the removed and implanted HCT/Ps are not the same (that is, the procedures "remove fat tissue but implant SVF").[10]

Interestingly, both of the stem cell products that unsuccessfully tried to claim the same-surgical-procedure exemption were based on processes that chemically isolated SVF from tissue.

Courts have not yet spoken on whether the same interpretation of the same-surgical-procedure exemption would apply to a similar therapy that utilizes mechanical processing, e.g., centrifugation.

Nevertheless, it is clear that the level and means of processing of the stem cells before they are returned to the patient's body, which informs whether the HCT/P is significantly processed before it is returned to the patient's body, appears to be a — if not the — pivotal factor under the same-surgical-procedure exemption.

**Predicting Where the Industry Goes Next**

Despite the FDA's relatively detailed, risk-based regulatory structure and the Ninth and Eleventh Circuits' recent decisions to hold stem cell developers to a higher regulatory standard, stem cell regulation could be significantly reeled back under the new administration.

The big question mark — for established biotech, manufacturers and providers alike — is on the commercial business of harvesting tissue, processing it and reintroducing it back into the donor.

Recently minted U.S. Department of Health and Human Services Secretary Robert F. Kennedy Jr. has heralded the need for increased stem cell research and publicly criticized the FDA's alleged suppression of stem cell therapies.[11]

To this end, RFK Jr. recently held a regenerative medicine roundtable, which allegedly included discussion on reducing regulatory oversight of therapies using adult stem cells.[12] Interestingly, the roundtable was held in a relatively secretive manner, unadvertised on the

HHS website, and news of the roundtable didn't officially break until almost two weeks after it was held.[13]

It was reported that the roundtable was attended by interim regulators, smaller biotech companies and reputable stem cell researchers, as well as heavy-hitting industry groups, such as the Alliance for Regenerative Medicine and the American Society of Gene and Cell Therapies.

However, the meeting was allegedly — and notably — missing representation from the larger regenerative biotech companies we would typically expect to see in a stem cell conversation of this importance.

Soon-to-be FDA Commissioner Marty Makary was also allegedly missing from the conversation, which may have been a strategic move by RFK Jr., as Makary has publicly called for increased premarket regulation for medical products and could pose a threat to RFK Jr.'s deregulatory efforts here.[14]

Of course, as the head of HHS, RFK Jr. will have considerable influence over the policies promulgated over the next four years, including stem cell therapy policies — not to mention the support of industry innovators and their lobbyists, hopeful to bring their HCT/Ps to market sooner, for cheaper — but Makary's counter-approach could jeopardize the initiative, or, at the very least, act as a guardrail to keep the deregulation of stem cell therapies from getting too far out of hand.

That said, RFK Jr.'s momentum toward facilitating the availability of stem cell therapies does align with values we saw under the previous Trump administration, which encompassed a facial preference toward the free use of one's own cells and treatment processes.

Most notably, the previous Trump administration championed the so-called Right to Try Act, which provides an alternative to the FDA's similar but slightly more restrictive expanded access pathway by permitting patients with life-threatening conditions to access investigational, unapproved treatment options.[15]

Although the Right to Try Act was touted by the former Trump administration as a major achievement for patient autonomy, it still included burdensome limitations that considerably hindered its effectiveness[16] — limitations that Republican lawmakers, and Trump himself, appear keen on removing during the current term.[17]

Most importantly from an industry perspective, the Right to Try Act only provides access to investigational drugs that have completed Phase 1 clinical trials, which, due to the resources required to conduct clinical trials — not to mention the fact that over 50% of investigational drugs fail at the Phase 1 stage[18] — effectively excludes any drugs that are developed by small- and medium-sized biotech companies.

The current legal landscape strengthens the opportunity to reel-back stem cell regulations. Trump has wasted no time in making good on his campaign promise of deregulation, recently issuing an executive order requiring federal agencies to eliminate 10 existing regulatory documents for every new regulatory action.[19]

If RFK Jr. and like-minded policymakers are looking for an excuse to lighten the regulatory burden on the stem cell industry, this executive order could be the perfect means to curtail the HCT/P regulations or minimize the conditions for meeting a partial of full regulatory exemption — which would be even more defensible in the post-Chevron era.

We do not need to remind readers that the U.S. Supreme Court **recently overturned** the decades-old Chevron doctrine, which previously required reviewing courts to defer to an agency's interpretation of a silent or ambiguous statute, in Loper Bright Enterprises v. Raimondo last year.[20]

Even under a reading of Loper that holds onto the spirit of Chevron — e.g., a ruling from the U.S. Court of Appeals for the Sixth Circuit in Moctezuma-Reyes v. Garland last year holding that agency deference should still be granted when a statute is broad but contains specific conferring language upon the agency[21] — a decision to restructure the HCT/P regulations could be relatively defensible.

After all, although PHSA Sections 351 and 361 are indeed broad, they do not directly speak to HCT/Ps — a subcategory created entirely by the FDA — so a reviewing court could easily elect not to defer to the interpretation relied upon by the Bush-era agency in establishing the regulatory structure in the first place.

Between the bullish stance on stem cell innovation held by RFK Jr., industry and policymakers, a push toward deregulation and patient autonomy by the new administration generally, and a judicial framework that lends little deference to precedent, we predict the perfect backdrop for government action aimed at expediting the premarket process for stem cell developers.

In the longer term, we could see the FDA rewrite the HCT/P regulations to lower the bar for companies to meet a full or partial regulatory exemption and, in the shorter term, we could see the agency simply halt enforcement of its existing HCT/P framework.

Although the FDA has issued one warning letter enforcing its HCT/P regulations under the new administration,[22] its Biologics/Internet/Surveillance/Other team has not issued an untitled letter in over a year, so the FDA may have already begun quietly exercising enforcement discretion in this area.

We could also see Congress codify a less stringent version of the FDA's framework establishing full or partial regulatory exemption for lower-risk stem cell therapies or amend the Right to Try Act to reduce the requirements for sick patients to obtain investigational drugs, and we could see courts interpret the requirements for full or partial regulatory exemption, e.g., the same-surgical-procedure exemption, more loosely to allow more stem cell developers to qualify.

Of course, Makary's influence could be a significant counter-force to at least the policy decisions that are within the FDA's control. As with most other policies under the new administration, it's a game of wait-and-see.

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[1] See FDA Guidance on Regulatory Considerations for HCT/Ps (July 2020).

[2] See PHSA 351.

[3] See PHSA 361; 21 CFR 1271.10.

[4] See 42 USC 264.

[5] See 21 CFR 1271.3(f); FDA Guidance, supra FN 1, at p. 9, 14-15.

[6] See FDA Guidance, supra FN 1, at p. 7.

[7] See 21 CFR 1271.3(c); see also FDA Guidance, supra FN 1, at p. 16.

[8] See FDA Guidance, supra FN 1, at p. 4.

[9] See 21 CFR 1271.15.

[10] See U.S. v. Cal. Stem Cell Treatment Ctr. Inc. , No. 22-56014 (9th Cir. 2024); United States v U.S. Stem Cell Clinic LLC , 998 F.3d 1302 (11th Cir. 2021).

[11] See X Post, RFK (Oct. 25, 2024).

[12] See RFK Jr. Convened Roundtable around Ways to Reduce Stem Cell Regulation, Endpoints (Mar. 14, 2025).

[13] See id.

[14] See What to Know About Marty Makary, Trump's Pick to Lead the FDA, Time (Mar. 6, 2025).

[15] See 21 USC 360bbb-0a; Expanded Access Versus Right-to-Try, Hosp. Pharm. 55(2):79-81 (2019).

[16] See FDA Reports Sparse Use of Trump's Right to Try Program, Politico (July 16, 2024).

[17] See Trump's Right to Try Program Sees Slow Uptake, Politico (July 16, 2024).

[18] See Why 90% of clinical drug development fails and how to improve it?, Pub. Med. (2022).

[19] See Unleashing Prosperity Through Deregulation.

[20] See Loper Bright Enterprises v. Raimondo , 603 U.S. 369 (June 28, 2024).

[21] See Moctezuma-Reyes v. Garland , 124 F. 4th 416 (6th Cir. 2024).

[22] See Letter to Sperm Bank, Inc., (Feb. 14, 2025).