Will Stem Cell Clinics Flourish Under RFK Jr.?

— Experts caution that deregulating these products may lead to patient harm

by <u>Rachael Robertson</u>, Enterprise & Investigative Writer, MedPage TodayMarch 20, 2025 After HHS Secretary Robert F. Kennedy Jr. <u>hosted a roundtable</u>opens in a new tab or window on reducing regulations on stem cells earlier this month, experts have raised concerns about a potential flourishing of questionable stem cell clinics that could harm patients.

Kennedy has made no secret of his support for stem cells, including them in his infamous post on Xopens in a new tab or window about FDA's "war on public health" coming to an end. Stem cells were among "suppressed" therapies including psychedelics, peptides, raw milk, hyperbaric therapies, chelating compounds, and more. While FDA has traditionally focused on stamping out questionable stem cell clinics through court cases and warning letters, the roundtable set a different tone toward these products, experts said.

Endpoints News reported opens in a new tab or window that the roundtable was convened last-minute, and HHS still hasn't shared any information publicly about what was discussed during the meeting.

While attendees included respected groups in medicine, such as the American Society of Gene & Cell Therapy and the American Academy of Orthopaedic Surgeons, one key figure was left out: Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research.

Marks has been influential in trying to improve the regulation of questionable stem cell treatments and clinics, according to Leigh Turner, PhD, executive director of the bioethics program at the University of California Irvine, who has long studied stem cell clinics.

At the same time, the guest list included Chadwick Prodromos, MD, a physician who runs businesses that sell consumers unproven stem cell treatments, Turner noted.

"I worry bringing someone like that in runs the risk of legitimizing what they're doing, giving that person credibility, and possibly distorting the conversation," Turner said.

"With a HHS Secretary big on deregulation ... the best case would have been a public hearing with meaningful conversation rather than a thrown-together roundtable."

The FDA has won two court casesopens in a new tab or window against questionable stem cell clinics, determining that fat-derived stem cell treatments are a drug and should be regulated as such. When it comes to injectable stem cell productsopens in a new tab or window, the FDA has often relied on warning letters, and one highly visible case in which the CEO of one such company was convicted opens in a new tab or window and is now serving prison timeopens in a new tab or window. Other clinicians have also been prosecuted opens in a new tab or window for delivering these treatments.