



## **ARM's Statement on the Departure of OTP Director Nicole Verdun and Deputy Director Rachael Anatol**

**Washington, DC – June 19, 2025**

We are deeply disappointed to learn that Office of Therapeutic Products (OTP) Director Nicole Verdun and Deputy Director Rachael Anatol have been placed on administrative leave. Over the past two years, Nicole and Rachael have modernized the FDA's regulatory approach to cell and gene therapy (CGT), earning the trust and respect of the CGT community and helping to ensure that the FDA was the global leader in this evolving field.

HHS Secretary Robert F. Kennedy, FDA Commissioner Marty Makary, and Center for Biologics Evaluation and Research (CBER) Director Vinay Prasad have all emphasized the importance of CGT for patients, for the success of the Make America Healthy Again (MAHA) movement, and for US global leadership in biotechnology. "We are absolutely committed to making sure the U.S. remains the center for cell and gene therapy research around the globe," HHS Secretary Kennedy said in a video released by HHS on June 6.

With five regulatory decisions pending on CGT products in 2025, and a burgeoning pipeline of nearly 2,000 CGT clinical trials ongoing globally, it is critical that CBER and OTP operate at the highest level of productivity, efficiency, and scientific rigor. Patients with severe diseases waiting for durable, potentially curative treatments do not have the luxury of time. ARM stands ready to partner with the Administration so that it can realize its ambitious vision for the future of CGT.

