



ARM Issues Statement on Dr. Peter Marks and the FDA's Office of Therapeutic Products

Washington, DC – March 29, 2025

Dr. Peter Marks has been a visionary leader, advocate for rare disease patients, and champion of cell and gene therapy (CGT) during his nine-year tenure as the Director of FDA's Center for Biologics Evaluation and Research. He made many significant contributions to the field over the years and will be missed.

Over the past 18 months, senior leaders at the FDA's Office of Therapeutic Products (OTP) have transformed their approach to advanced therapies by hiring critical scientific personnel and dramatically modernizing the regulatory framework to keep up with the ever-expanding CGT pipeline. The first gene therapies for rare genetic diseases and CAR-T therapies for blood cancers were approved during the first Trump Administration, and the number of approved CGTs has now reached 44 during the second term. Patients who often have no other treatment options cannot afford for OTP's reform efforts to slow as more durable and potentially curative therapies for rare diseases, cancers, and even prevalent diseases are nearing regulatory decisions.

The US is the global leader in CGT innovation, but a fierce global competition for talent, expertise, and investment is underway. Sustaining OTP's gold-standard approach to CGT regulation is critical to the United States' global leadership position. As the Administration and FDA consider resource allocation and restructuring decisions, we strongly encourage leaders to build on recent reform and modernization efforts and enable a culture that attracts, retains, and develops top scientific talent.

