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Just Prior to Leadership Change, FDA Announces Public Workshops to Advance Dialogues on HCT Product Development and Optimizing Pregnancy Registries

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In the final stretch of the Biden administration, the Food and Drug Administration (FDA) laid the groundwork for continued engagement with the public on two challenging areas of product development, each of which is of high interest to patients, clinical communities, industry stakeholders and policy-makers in Congress.

The FDA is pressing forward on supporting human cell therapies and tissue-based product development. On January 17, 2025, the FDA issued a notice in the *Federal Register* announcing a virtual public workshop entitled "Cell Therapies and Tissue-Based Products: A Public Workshop on Generating Scientific Evidence to Facilitate Development" to fulfill Section 3205 of the Food and Drug Omnibus Reform Act of 2022 (P.L. 117-328), which required the FDA to hold a public workshop to discuss the best practices on generating scientific data necessary to further facilitate the development of certain human cell-, tissue- and cellular-based medical products (HCT/P).

The FDA's HCT/P workshop is scheduled to be held on February 25, 2025, and topics to be discussed during the workshop include (1) the current state of the science for tissue and cell-derived therapies and explore what challenges remain as the field continues to mature; (2) nonclinical work to assess the safety of cell therapy products in support of product development; (3) considerations for characterization of cell therapy products to help ensure manufacturing quality during product development and through commercialization; (4) clinical considerations and future directions for locally administered cell therapies under

investigation for niche indications; and (5) considerations for a revised risk-based HCT/P framework. The deadline for submitting comments on this workshop is March 18, 2025.

In addition, by announcing a public workshop on optimizing pregnancy registries, the FDA is focusing on another challenging areas of product development while also pursuing a Prescription Drug User Fee Act (PDUFA) commitment. In the most recent reauthorization of PDUFA commitment letter, the FDA agreed to develop a framework describing how to use data optimally from different types of post-approval pregnancy safety studies. On January 17, 2025, the FDA issued a notice announcing a public workshop entitled "Optimizing Pregnancy Registries" to be held on March 27 and 28. This public workshop is being held in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation program.

The purpose of the public workshop is to discuss challenges in designing and implementing pregnancy registries and consider innovative approaches to improve the design and conduct of pregnancy registries. In announcing the workshop, the FDA announced the it will discuss the current status of pregnancy registries and challenges in gathering data regarding the safety of drug and biological products used during pregnancy, perspectives from interested parties (FDA, academia, industry, health care providers and patients) on strategies to improve the design and conduct of pregnancy registries, and innovative approaches/models to facilitate the conduct of pregnancy registries, including disease-based multi-product, multi-sponsor pregnancy registries.

Both of these public workshops provide opportunities for stakeholders to engage with the FDA on areas of product development for patients and also demonstrate how the agency's perpetual work on behalf of patients and public health spans administrations.

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Food and Drug Administration (FDA)