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FDA Seeks Feedback on Patient-Focused Drug Development

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In December 2016, the bipartisan 21st Century Cures Act (P.L. 114-255) was enacted, marking a pivotal milestone in advancing a patient-focused drug development (PFDD) paradigm. This law directed the Food and Drug Administration (FDA) to develop and implement strategies to solicit view of patients during the medical product development process and consider the perspectives of patients during regulatory discussions. Over the past decade, FDA has steadily taken steps to implement the 21st Century Cures Act patient-focused drug development provisions, including through meetings by which patients, caregivers, family members and patient advocates, among others, have been able to provide information about patients' experiences with a disease or condition. The opportunity to provide such feedback through these patient-focused meetings is a key pillar of the agency's patient-focused drug development engagement.

On May 1, 2026, FDA published a notice in the *Federal Register* requesting information and public comment on how PFDD meetings have impacted drug development efforts. The notice establishes a public docket and FDA invites input from interested parties, including patient organizations, medical product developers, health care providers and academic researchers to submit comments by June 30, 2026. FDA seeks to better understand how patient input from FDA-led and externally led PFDD meetings has informed stakeholder activities such as research, product development and patient care, outside of specific regulatory decisions, and acknowledges insights generated through PFDD meetings can help inform medical product development, research priorities and FDA's broader regulatory oversight. In addition to requesting that respondents describe any other outcomes or effects

resulting from PFDD meetings, FDA specifically seeks input on the following questions:

1. How have PFDD meetings informed patient communities and stakeholder engagement activities?

2. What scientific questions, research initiatives or identified gaps in the understanding of a disease or condition have resulted from PFDD meetings?

3. In what ways has patient input from PFDD meetings informed medical product development programs or strategies (e.g., endpoint development, clinical trial design, identification of unmet needs, industry partnerships)?

4. How has patient input gathered during PFDD meetings been integrated into or otherwise affected clinical practice?

As the ten-year anniversary of the enactment of the 21st Century Cures Act approaches, it is a natural inflection point to assess the impact of the PFDD provisions. However, this request for information (RFI) may also inform the agency's broader efforts to modernize and optimize clinical trial and regulatory decision making, as this RFI is seeking feedback on what ways patient input from PFDD meetings informed medical product development areas (endpoint development, clinical trial design, areas of unmet needs) that transcend patient populations suffering from a range of diseases and conditions, including rare diseases. The feedback to this RFI may also inform the next Prescription Drug User Fee Act (PDUFA) reauthorization, given the legislative history and ongoing interests in patient-focused medical product development and prior focus in both the PDUFA VI and VII reauthorizations.

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