



## **FDA Presses Forward on Incorporating Patient Preferences in Device Decision Making, Releases Updated Final Guidance**

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On March 30, 2026, the Food and Drug Administration (FDA) published a final guidance entitled “Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle.” The guidance provides updated recommendations to industry and FDA on how and when voluntary patient preference information (PPI) may be considered by FDA staff in decision making relating to devices. PPI is not required for FDA’s consideration as part of FDA decision making, but FDA may find it valuable to consider patient viewpoints when the information meets applicable legal requirements. In addition, FDA encourages industry and other interested parties to consider patient experience data in device development and evaluation, including data relating to patient preferences for outcomes and treatments. FDA acknowledges that patient perspective and personal experiences can help FDA evaluate the benefit-risk profile of certain devices throughout the total product life cycle.

The objectives of this guidance are to encourage the submission of PPI to aid FDA in decision making, outline recommended qualities of PPI studies, provide practical recommendations for collecting and submitting PPI to FDA, and discuss FDA’s inclusion of PPI in its decision summaries and provide recommendations for the inclusion of PPI in device labeling.

The guidance replaces FDA’s 2016 guidance “Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling.”

The final guidance fulfills a commitment in Section V.E. of the Medical Device User Fee Amendments Performance Goals and Procedures, Fiscal Years 2023 Through 2027 (MDUFA V) to update the 2016 PPI Guidance with pragmatic insights and to address common questions for those interested in the voluntary use of PPI in regulatory submissions. Patient engagement in the development of medical products has been a recurring bipartisan area of interest for policymakers for many years, including as part of previous user fee reauthorizations and the 21st Century Cures Act. As Congress prepares to consider reauthorizing MDUFA, currently set to expire at the end of September 2027, policymakers are likely to continue to consider how to advance a patient-focused medical product development paradigm and FDA's progress in implementing related MDUFA V commitments.

## Categories



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