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MEDICAL DEVICE INNOVATION CONSORTIUM RELEASES FIRST-OF-ITS-KIND PATIENT PREFERENCE FRAMEWORK

Washington, DC, May 13- Medical Device Innovation Consortium (MDIC) released the first-of-its-kind Framework report, **“A Framework for Incorporating Information on Patient Preferences Regarding Benefit and Risk into Regulatory Assessments of New Medical Technology,”** (<http://mdic.org/pcbr/>) on how to incorporate patient preferences into the development and submissions of medical devices.

The Framework report is a result of collaborative work that came after the U.S. Food & Drug Administration (FDA) issued a guidance document in 2012 “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications.” (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm267829.htm>). This Benefit-Risk Guidance discusses how the patient’s perspective on benefits and risks is valuable in the regulatory assessment of new medical devices, but does not provide detail on when or how to collect such information. MDIC undertook its Patient Centered Benefit-Risk (PCBR) Project both to catalog the methods available to assess patient preferences and to create a framework to guide thinking about when and how to collect information on patient preferences in the development and regulatory evaluation of medical devices.

The MDIC Patient Centered Benefit-Risk (PCBR) Framework Report presents the result of this MDIC effort. The report includes: a discussion of background concepts and definitions; factors to consider in deciding in what situations patient preference information might be valuable; when in the product development lifecycle it may be useful to collect such information; a summary of the methods available to assess patient preferences quantitatively and factors to consider in designing a patient preference study; regulatory considerations regarding the submission of such information; and areas for future work in the field of patient preference assessment. A major appendix to the report includes the “Catalog of Methods for Assessing Patient Preferences,” the first compendium of the range of methods available to evaluate patient preferences quantitatively.

MDIC President and CEO, Bill Murray notes, “With the release of the Patient Centered Benefit-Risk Framework Report, our MDIC public-private partnership has proven the power of multi-stakeholder collaboration in bringing the patient voice to medical technology innovation. We are realizing our mission of advancing regulatory science for the benefit of patients.” The Framework Report was made possible through the collaboration of a dedicated group of individuals comprised of MDIC member organizations, FDA, and experts in decision science and preference assessment methods from academia and other organizations.

The MDIC PCBR Framework Report represents an initial thought piece on how sponsors might use information on patient preferences regarding the benefits and risks of a new technology to enhance regulatory submissions. The report is not a step-by-step guide to undertaking patient preference studies; it does not suggest that such information would be useful in all situations; nor does it suggest changing any current regulatory approval standards or processes. Rather, the Framework Report is intended help sponsors and FDA think about how to better incorporate the patient’s perspective into the existing regulatory approval process.

“The FDA is committed to integrating the patient voice into its regulatory decision-making and is pleased with the significant progress that MDIC has made in laying the groundwork for this work,” said Robert M. Califf, M.D., FDA Deputy Commissioner for Medical Products and Tobacco. “Patient Groups, industry, and others are encouraged to interact with the agency early to discuss how patient preference information can be used for device development and evaluation, an approach that will lead to better devices that can be used more effectively in practice.”

Medical Device Innovation Consortium (MDIC) is a nonprofit public-private-partnership composed of nearly 50 member organizations located in St. Louis Park, MN. Founded in 2012, MDIC is actively engaged in advancing the regulatory science of medical devices through development of tools, methods and approaches that facilitate faster, safer, and more cost-effective development, assessment and review of important new technologies for the benefit of patients.

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