Published on *The National Law Review* https://natlawreview.com

# The Role of Patient Preference in Medical Device Evaluation

Article By:

Health Care and Life Sciences Practice Group

When we think about the top players in the medical device development space, we often see device company sponsors, clinicians, scientists, and FDA regulators as the ones driving the process. But what about the patient perspective? Does that get factored in?

On May 3, 2019, FDA established a docket to collect public input on a proposed list of patient preference-sensitive areas for medical device review, and posed certain related questions (comments are due July 2, 2019). By identifying these key areas (which it committed to as part of the reauthorization of the Medical Device User Fee Amendments of 2017 (MDUFA IV)), FDA hopes to advance patient input, which can help inform and improve regulatory decision-making. FDA has grouped these proposed patient-preference sensitive areas (full list available here) into the following four umbrella categories:

1. Patient values in diagnosis and treatment
2. Relevant clinical endpoints for specific patient populations
3. Patient benefit-risk tradeoffs for treatment options or diagnostic approaches
4. Impact of uncertainty in benefit-risk tradeoffs

Stepping back for a moment, though, it's important to understand what exactly patient preference information is and how FDA has addressed patient preference information to date.

## What is Patient Preference Information (PPI)?

FDA defines PPI as "qualitative or quantitative assessments of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions." Put simply, PPI can help inform what's important to patients and can be useful in evaluating a device's benefit-risk profile, particularly when treatment options are "preference sensitive" (i.e., multiple treatments exist and no option is clearly superior or the evidence supporting one option over the others is uncertain).

## What Efforts has FDA Previously Undertaken to Advance the Patient Perspective?

Since 2013, FDA has taken several actionable steps to recognize the voice of patients, including the following:

- 2013 – FDA launched the Patient Preference Initiative, and hosted a public workshop to discuss ways to incorporate patient preferences on device benefit-risk trade-offs into Center for Devices and Radiological Health ("CDRH") decision-making, and advance the science of measuring patient and provider treatment preferences.

- 2015 – FDA announced the first Patient Engagement Advisory Committee (PEAC), supported by CDRH, which provides advice to the FDA Commissioner on complex issues relating to devices and their use by patients, with the goal of increasing integration of patient perspectives into the regulatory process.

- 2016 – FDA released final guidance entitled "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"

- 2017 – FDA co-hosted a workshop presenting current progress on incorporating PPI into medical product reviews and how PPI can be collected and presented (among other topics).

As patients become increasingly interested and engaged in their health care decisions, it makes a lot of sense for their perspectives to be considered by regulators who are evaluating the benefits and risks of proposed products.  Of course, however, it is important that patient preference information is accurately measured and appropriately weighted in the decision-making process. To that end, FDA advises sponsors that are considering patient preference studies to consult with the Agency early on in the process.



National Law Review, Volume IX, Number 143