Involving Patients in Assuring Safe & Effective Medical Device Use

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Patients are at the Heart of All We Do

CDRH Vision:
Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance, first in the world.
Evolution of the Patient’s Role

Traditional Medicine:
Provider-led treatment decision-making

Emerging Diseases:
Patient advocacy for availability of and access to new treatments

The Internet:
Patient empowerment through information

The Future Today:
Patient-Provider partnership in treatment decision-making
We interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.

1. Promote a culture of meaningful patient engagement by facilitating CDRH interaction with patients.

2. Increase use and transparency of patient input as evidence in our decision-making.
Where is Patient Input Useful?

- Patient-Informed Needs
  - Discovery + Ideation
- Pre-Clinical
  - Patient Preference Information for Benefit-Risk Decisions
- Clinical
  - Patient-Informed Clinical Trial Design, Patient Reported Outcomes
- Regulatory Decision
- Product Launch
  - Communicating Benefit-Risk Information to Patients
- Post-Market Monitoring
  - Patient-Centered Outcomes
Promote a culture of meaningful patient engagement by facilitating CDRH interaction with patients

PATIENT ENGAGEMENT
Model for Culture Change

Promote a culture of meaningful patient engagement by facilitating **CDRH interaction with patients**

Interaction  Meaningful engagement  Partnership
Strengthening a Culture of Patient Engagement

• Patient Engagement Advisory Committee
• PITCH & PROPEL Staff Competitions
• Town Hall Meetings
• Patient & CarePartner Connection
• Patient Organization Awareness Day
Patient Science and Engagement Competitions

Purpose: To facilitate CDRH staff engagement and capacity building

**PITCH Patient Engagement Competition**

- Funding for staff to hold meaningful patient engagement activities
- Staff determined and pitched what they considered meaningful engagement

**Propel Patient Science Competition**

- Funding for staff research to advance the science of patient input
- Staff determined areas where PROs and PPI would be of most benefit in their work

Over 75 staff from across the Center competed, and hundreds participated, in inaugural contests held in early 2016.
Investing in Culture: Patient Focused

MDUFA IV Agreement in Principle

Patient input in clinical trials

Patient preference information (PPI)

Patient reported outcomes (PRO)
Patient Engagement: Employee Comments

“Hearing patient experiences and suggestions is extremely valuable to our mission.”

“Puts a needed human face to our actions.”

“Hearing patients’ personal experience was extremely powerful and moving.”
Increase use and transparency of patient input as evidence in CDRH decision-making

SCIENCE OF PATIENT INPUT
Patient Input

Patient input includes a range of different types of information:

- Anecdotal comments in correspondence to the FDA
- Testimony at Advisory Committee meetings
- Patient opinions expressed publicly including through social media
- Patient responses to qualitative *ad hoc* surveys
- Quantitative measurements of patient-reported outcomes
Patient Perspective Studies

Patient Perspective studies

Patient Preference Information (PPI)
- Patient perspective on trade-offs of benefits and risks

Patient-Reported Outcomes (PROs)
- Health status reported from patient without involvement of physician
What can PROs and PPI tell us?

**Patient Reported Outcomes (PRO):**
- Endpoints in regulatory studies
- Outcomes to monitor postmarket
- Interest to payers, providers, patients

**Patient Preference Information (PPI):**
- Inform endpoints or effect size for regulatory studies
- Inform subgroup considerations
- Labeling changes / expanded indications
Thank You