The Importance of the Patient Voice

- Insights on issues, needs and priorities that are important to patients and caregivers
- Diverse opinions and experiences
- Insights on risk tolerance and potential benefit
- Real world experience

Patients are at the heart of FDA’s work!
Evolution of Patient Engagement at the FDA

1988 - Office of AIDS Coordination established

1993 - Office of AIDS Coordination renamed to Office of AIDS and Special Health Issues (OASHI) and broadened to include patients with cancer and other serious and life-threatening diseases
- First FDA Patient Representative® served on an advisory committee

1996 - FDA Patient Representatives® received voting rights on advisory committees

2001 - Patients and consumers encouraged to report medical product problems using FDA’s existing MedWatch system

2008 - A section of the FDA website is created specifically For Patients
- Patient-Focused Drug Development (PFDD) initiative launched

2012 - Internal working group examines ways to increase patient involvement in FDA processes
- Consumer-friendly form introduced in FDA’s MedWatch system to report medical product problems

2013 - Patient Preference Information (PPI) framework and guidance for medical device decision making
- Patient Engagement Advisory Committee (PEAC) announced in the Federal Register

2015 - Patient Engagement Cluster created
- First Patient Council (internal) meeting held

2016 - Office of Patient Affairs (formerly Patient Affairs Staff) established in the Office of the Commissioner
- Memorandum of Understanding with National Organization For Rare Disorders (NORD) launched the FDA Patient Listening Session pilot program
- Patient Engagement Collaborative (PEC) launched with Clinical Trials Transformation Initiative (CTTI)
- Center for Devices and Radiological Health (CDRH) Patient & Caregiver Connection (P&CC) program launched
- Public Workshops on PFDD guidances and drafts released

2017 - Patient Affairs Staff (PAS) online webform, Patients Ask FDA
- PFDD Workshop on Guidance 4
- Draft PFDD Guidance 2 released

2018 - COVID-19 Patient Resources Page launched
- Final PFDD Guidance 1 released
- Muscular Dystrophy Association webinar on COVID-19
- FDA and NORD Listening Session on COVID-19 Impact on Rare Disease Communities

2019 - Office of Patient Affairs name changed from Patient Affairs Staff
Office of Patient Affairs

Who we are

What we do

- Small team in the Office of the Commissioner dedicated to providing an inviting, welcoming and meaningful experience for patient communities to engage with the FDA

- Lead patient engagement activities across the medical product Centers through:
  - Cross-cutting programs and activities
  - Public-private collaborations and partnerships
  - Enhance external communication platforms
FDA Patient Listening Session program
An avenue for engagement
What is an FDA Patient Listening Session?

• One of the ways that patients can share their experience living with and managing a disease/condition or health-related experience

• Patients & caregivers can talk directly with FDA scientific staff

• A resource for FDA’s medical product Centers to quickly engage with patients or their advocates

• Starting point to inform regulatory decision-making & early-stage R&D

• Includes staff from multiple (2+) medical product centers
What do Patient Listening Sessions look like?

Understanding FDA’s Patient Listening Sessions

✓ ARE

• Non-public, non-advisory discussions between FDA staff and patients, their caregivers, and/or their advocates
• 1 to 1.5 hour meetings
• Via phone, in person at FDA or a mix of the two
• Meant to facilitate expeditious sharing of patient or advocate perspectives on:
  - Disease burden
  - Treatment burden
  - Impact on daily activities
  - Priorities to consider in medical product development programs

✗ Are NOT

• Open to industry
• Avenues for the endorsement of specific medical products
• Able to guarantee representative or comprehensive perspectives on disease or treatment burden
• Meant to take the place of other patient input and engagement processes, e.g., the FDA Patient Representative Program, Patient-Focused Drug Development (PFDD) Meetings
FDA Patient Listening Session program basics

• Hosted in collaboration with National Organization for Rare Disorders (NORD) and the Reagan-Udall Foundation for the FDA

• 40+ Listening Sessions held since late 2018

• 2 types: Can be requested by FDA or the patient community

• Listening Sessions are not recorded, but meeting summaries are available on the Patient Listening Session page

www.fda.gov/PatientListeningSessions
Resources & Tools
Patient engagement at FDA
**FDA’s Medical Product Center Patient Engagement Initiatives**

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**Center for Biologics Evaluation and Research (CBER)**

- Interactive Meetings with Patients
- **CBER Workgroups:**
  - CBER Patient Engagement Workgroup
  - CBER Rare Disease Coordinating Committee
  - CBER Science of Patient Input (SPI) Team
Questions & Meeting Requests

www.fda.gov/PatientsAskFDA