Evolution of Patient Engagement at the FDA



2020 - 2019 - 2018 - 2017

- COVID-19 Patient resources page Launched
- Final PFDDguidance 1 released
- Muscular Dystrophy Association webinar on COVID-19
- FDA and NORD
 listening session on
 COVID-19 impact on
 rare disease
 communities

- FDA launchedPatients Ask FDA
- PFDD workshop on guidance 4
- Draft PFDDguidance 2 released
- Memorandum of
 Understanding with
 National
 Organization
 For Rare Disorders
 launched the
 Patient Listening
 Session pilot
 program
- Patient Engagement
 Collaborative
 launched with
 Clinical Trials
 Transformation
 Initiative
- Center for Devices
 and Radiological
 Health <u>Patient &</u>
 Caregiver
 Connection
 program launched
 public workshops
 on PFDD guidances
 and drafts released

- Patient Affairs Staff
 (PAS) established in the Office of the Commissioner
- Public Workshop on PFDD guidance
- PEAC meetings regarding medical devices

2012 - 2013 - 2015 - 2016

- FDA launched <u>For</u>Patients on the web
- Patient-FocusedDrug Development(PFDD) initiativelaunched
- Internal working group examined ways to increase patient involvement in FDA processes
- Consumer-friendly form introduced in FDA's MedWatch system to report medical product problems
- Patient Preference
 Information
 framework and
 guidance for
 medical device
 decision making
- Patient Engagement
 Advisory Committee
 (PEAC) announced
 in the Federal
 Register
- FDA and European
 Medicines Agency
 Patient Engagement
 Cluster created
- First PatientCouncil (internal)meeting held

008 - 2001 - 1996 - 1993 - 1993

- Patients and consumers encouraged to report medical product problems using FDA's existing MedWatch system
- First FDA Patient
 Representative
 Program® role
 expanded to serve as
 consultants to
 scientific and
 regulatory reviewers
 - First FDA Patient
 Representatives®
 received voting
 rights on advisory
 committees
- Office of AIDS
 Coordination
 renamed to Office of
 AIDS and Special
 Health Issues and
 broadened to include
 patients with cancer
 and other serious
 and life-threatening
 diseases

Office of AIDS

established

Coordination

First FDA Patient
Representative®
served on an
advisory committee