Evolution of Patient Engagement at the FDA

2020
- 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
- FDA launched Patients Ask FDA
- PFDD workshop on guidance 4
- Draft PFDD guidance 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 Patient & Caregiver Connection program launched
- Public Workshop on PFDD guidance
- PEAC meetings regarding medical devices

2018
- Patient Affairs Staff (PAS) established in the Office of the Commissioner
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2016
- FDA and European Medicines Agency Patient Engagement Cluster created
- First Patient Council (internal) meeting held
- First Patient Representative® served on an advisory committee

2015
- Patient Preference Information framework and guidance for medical device decision making
- Patient Engagement Advisory Committee (PEAC) announced in the Federal Register
- 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 Coordination established

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