This program is sponsored by the International Foundation for Gastrointestinal Disorders. The views and opinions expressed in this presentation do not necessarily reflect the official position of IFFGD. Information and resources shared should not replace any medical care you are receiving. Finally, it is important to always consult with your doctor or other health care provider before making decisions about your treatment.

The following slides were presented during the educational portion of IFFGD’s 2020 Virtual Advocacy Event. To view this presentation and the all videos available during this program, please visit https://bit.ly/Adv_Edu.
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

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<tbody>
<tr>
<td>Office of AIDS Coordination established</td>
<td>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</td>
<td>FDA Patient Representative program established</td>
<td>FDA Patient Representative Program received voting rights on advisory committees</td>
<td>Patients and consumers encouraged to report medical product problems using FDA’s existing MedWatch system</td>
<td>A section of the FDA website is created specifically for Patients</td>
<td>Internal working group examines ways to increase patient involvement in FDA processes</td>
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<td>First FDA Patient Representative served on an advisory committee</td>
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<td>Consumer-friendly form introduced in FDA’s MedWatch system to report medical product problems</td>
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<tr>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
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<tbody>
<tr>
<td>Patient Preference Information (PPI) framework and guidance for medical device decision making</td>
<td>FDA and European Medicines Agency (EMA) Patient Engagement Cluster created</td>
<td>First Patient Council (internal) meeting held</td>
<td>Memorandum of Understanding with National Organization For Rare Disorders (NORD) launched the Patient Listening Session pilot program</td>
<td>First Patient Council (internal) meeting held</td>
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<td>Patient Engagement Advisory Committee (PEAC) meetings regarding medical devices</td>
<td>PAS established in the Office of the Commissioner</td>
<td>Public Workshop on PFDD guidance</td>
<td>Patient Engagement Collaborative (PEC) launched with Clinical Trials Transformation Initiative (CTTI)</td>
<td>Public Workshops on PFDD guidance and drafts released</td>
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<td>Center for Devices and Radiological Health (CDRH) Patient &amp; Caregiver Connection (P&amp;CC) program launched</td>
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<td>Public Workshop on PFDD</td>
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Patient Affairs Staff (PAS)

Patient Affairs Staff (PAS), Office of the Commissioner

- Lead patient engagement activities across the medical product Centers

- Public-private collaborations and partnerships
- Cross-cutting programs and activities
- Enhance external communication platforms

PAS Programs and Activities

- FDA/EMA Patient Engagement Cluster
- Patient Engagement Collaborative
- FDA Rare Disease Patient Listening Sessions
- Enhancing communications
FDA and EMA Patient Engagement Cluster

Mutual exchange on:
- Engaging and involving patient stakeholders
- High profile topics of mutual interest
- Collaborations to enhance engagement

Publication:

Patient Engagement Collaborative (PEC)

- FDA & Clinical Trials Transformation Initiative (CTTI)
- EMA’s Patients’ and Consumers’ Working Party (PCWP) model
- **Purpose:** Topics about enhancing patient engagement in medical product development and regulatory discussions
Patient Listening Sessions

- Memorandum of Understanding with the National Organization for Rare Disorders (NORD)
- Inform regulatory decision-making
- Educate review staff
- Help patients and their advocates understand the FDA’s work
- Starting point to inform early stage R&D

FDA Rare Disease Patient Listening Sessions

**Two Types:**

1. FDA-requested
2. Patient-requested

Request a Patient Listening Session: [www.fda.gov/PatientsAskFDA](http://www.fda.gov/PatientsAskFDA)

Patient Listening Sessions Webpage: [www.fda.gov/PatientListeningSessions](http://www.fda.gov/PatientListeningSessions)
Enhancing Communication with Patients

Submit Questions & Meeting Requests

www.fda.gov/PatientsAskFDA
FDA Patient Representative Program®

FDA Patient Representative
- provide direct input to the Agency’s decision-making process
- over 300 diseases and conditions represented
- participate on FDA Advisory Committees and in review division assignments

Criteria for becoming an FDA Patient Representative:
- Know your disease
- Be active in the community
- Know your treatment
- Avoid conflicts of interest
- Remain objective
- Be able to discuss your views

PATIENT RESOURCES
Patient Engagement Contacts Across FDA

FDA Patient Affairs Staff: PatientAffairs@fda.gov

FDA Patient Representative Program: FDAPatientRepProgram@fda.hhs.gov

Patient Engagement Meeting Requests: CDRH_PatientMeetings@fda.hhs.gov

Patient Engagement Initiatives: CDRH_PatientEngagement@fda.hhs.gov

CDRH's Division of Industry and Consumer Education: DICE@fda.hhs.gov

Office of the Commissioner

Center for Biologics

Center for Devices

Center for Drugs

CBER's Patient Engagement Initiatives: CBERPatientEngagement@fda.hhs.gov

Office of Communication, Outreach and Development: OCOD@fda.hhs.gov

Professional Affairs and Stakeholder Engagement: CDERPASE@fda.hhs.gov

CDER Division of Drug Information: DrugInfo@fda.hhs.gov

Patient Focused Drug Development: patientfocused@fda.hhs.gov

www.fda.gov/PatientsAskFDA

www.fda.gov/PatientsAskFDA

COVID-19

INFORMATION & UPDATES

www.fda.gov

For Patients

Learn about COVID-19, treatment options, public health and more.

For Healthcare Professionals

Learn about COVID-19, treatment options, public health and more.

www.fda.gov/patients
Report Adverse Events to MedWatch

- **Safety info IN:**
  - Send information you observe or experience from regulated medical products to FDA

- **Safety info OUT:**
  - Stay up-to-date on recently reported safety information from FDA

www.fda.gov/MedWatch

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**Acronyms**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>AC or ADCOM</td>
<td>Advisory Committee</td>
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<tr>
<td>CBER</td>
<td>Center for Biologics Evaluation and Research</td>
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<tr>
<td>CDER</td>
<td>Center for Drug Evaluation and Research</td>
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<tr>
<td>CDRH</td>
<td>Center for Devices and Radiological Health</td>
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<tr>
<td>CTTI</td>
<td>Clinical Trials Transformation Initiative</td>
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<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
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<td>MOU</td>
<td>Memorandum of Understanding</td>
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<td>NORD</td>
<td>National Organization for Rare Disorders</td>
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<td>PAS</td>
<td>Patient Affairs Staff</td>
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<td>PEAC</td>
<td>Patient Engagement Advisory Committee</td>
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<td>PFDD</td>
<td>Patient Focused Drug Development</td>
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<tr>
<td>PPI</td>
<td>Patient Preference Initiative</td>
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www.fda.gov
When in doubt...contact Patient Affairs!

- Andrea Furia-Helms
- Susan Chittooran
- Wendy Savit
- Lauren Bateman

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301-796-8460
www.fda.gov/Patients
@FDAPatientInfo