

Patient Affairs Staff Overview of FDA Initiatives

Ashley Channels, Pharm.D.
Program Coordinator
Patient Affairs Staff
Office of the Commissioner

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!*

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 FDA
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- Lead patient engagement activities across the medical product Centers through:
 - Cross-cutting programs and activities
 - Public-private collaborations and partnerships
 - Enhance external communication platforms

Patient Listening Sessions

Rare Diseases



- Inform regulatory decision-making
- Patients & caregivers can talk directly with FDA scientific staff
- Patients can share their experiences living with and managing a disease or condition
- Help patients and their advocates understand the FDA’s work
- Starting point to inform early-stage R&D
- Memorandum of Understanding with the National Organization for Rare Disorders (NORD)

Patient Listening Sessions



Types of Listening Sessions

1. **FDA-requested:** specific questions to ask of a particular patient sub-population
2. **Patient-led:** patient community wants to share their experiences and perspectives with the FDA



Purpose

Patient Engagement Collaborative (PEC)

- Opportunity for the patient community to discuss and exchange views and perspectives (ideas and experiences)
- PEC member meetings are typically held virtually (teleconference or webinar) up to six times per year
- Activities of the PEC may guide some FDA and CTTI activities not intended to advise
- Not directly related to regulatory policy decisions and are non-committal
- Do not discuss specific medical products or treatments



Patient Engagement Collaborative (PEC)

- Hosted by Clinical Trials Transformation Initiative (CTTI) and supported by FDA's Patient Affairs
- Modeled from EMA's Patients' and Consumers' Working Party (PCWP)
- Comprised of 16 wide-ranging representatives of the patient community (patients, caregivers, patient advocates)
- Serve 2-year terms
- Mutual exchange on:
 - Increasing bi-directional communication
 - Educating patient communities
 - Enhancing patient engagement



Resources: Patient Engagement Across FDA

Office of the Commissioner

FDA Patient Affairs Staff
PatientAffairs@fda.hhs.gov

FDA Patient Representative Program
FDAPatientRepProgram@fda.hhs.gov

Oncology Center of Excellence
FDAOncology@fda.hhs.gov

Center for Drugs (CDER)

CDER 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

Center for Biologics (CBER)

CBER Patient Engagement Initiatives
CBERPatientEngagement@fda.hhs.gov

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

Center for Devices (CDRH)

CDRH Patient Engagement Initiatives
CDRH_PatientEngagement@fda.hhs.gov

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

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

Resources: Patient Affairs

Patient Listening Sessions

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/fda-patient-listening-sessions>

Patient Engagement Collaborative (PEC)

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/patient-engagement-collaborative>

Patients: Ask FDA Questions & Meeting Requests

www.fda.gov/PatientsAskFDA

Contact

PatientAffairs@fda.gov

301-796-8460

www.fda.gov/Patients