

Patient Affairs Staff (PAS)

Who We Are

The Patient Affairs Staff (PAS) in the Office of Medical Products and Tobacco supports cross-cutting patient engagement activities across the FDA. PAS works closely with FDA's medical product centers, other FDA offices, and patient communities to complement and support ongoing FDA [patient engagement initiatives](#).

Vision

Our vision is to work toward a unified FDA culture and structure that enhances patient engagement throughout the medical product development lifecycle and regulatory decision-making to advance safe and effective medical products.

Mission

Our mission is to coordinate and support patient engagement activities across the medical product centers to facilitate awareness and collaboration with patients, their advocates and the FDA under [FDASIA section 1137](#), [FDARA](#) and [21st Century Cures](#).

What We Do

Public and Private Collaborations and Partnerships

- [FDA and European Medicines Agency \(EMA\) Patient Engagement Cluster](#): FDA and EMA share best practices about involving patients in discussions around the review of medical products.
- [Patient Engagement Collaborative \(PEC\)](#): FDA and the Clinical Trials Transformation Initiative (CTTI) established a work group with patient advocates to discuss ways to increase opportunities for patient engagement with FDA, including giving patients a voice in medical product development and other regulatory discussions.

Cross-center Programs and Activities

- [Rare Disease Listening Sessions](#): FDA and the National Organization for Rare Disorders (NORD) are piloting a series of rare disease listening sessions that allow patients and caregivers to share their experiences and most urgent needs with FDA staff to help inform medical product development.
- [FDA Patient Council](#): The FDA-wide Patient Council brings together Centers and Offices to better coordinate and integrate the role of patient perspectives in FDA's decision-making process.

Enhancing Communications with Patients & Caregivers

- Creating a new, central portal for patients and their advocates to submit questions and meeting requests to FDA
- Developing and improving FDA patient resources, such as through the development of a video series
- Leading outreach to patients, caregivers, and advocacy groups through social media and other means of communication

Want to learn more? FDA's Patient Affairs Staff can help!

Connect with Us

 www.fda.gov/ForPatients

 (301) 796-8460

 PatientAffairs@fda.hhs.gov

 @FDAPatientInfo



Patient Engagement at FDA: Your Voice Matters

Are you a patient who wants to get involved with FDA? Your voice as a patient or caregiver is important to us! As a patient, you have a unique perspective on your disease or condition, the treatments you use, and the medical procedures you go through. FDA's medical product centers and offices offer many ways for patients to get involved, including:

- **FDA Patient Representative ProgramSM**: FDA Patient Representatives provide FDA with the unique voice of patients and family members who are affected by a disease or condition in FDA Advisory Committees and panels, and in review division discussions.
Contact: FDAPatientRepProgram@fda.hhs.gov
- **Patient Focused Drug Development Initiative (PFDD)**: The goal of PFDD is make sure that patients' experiences, perspectives, needs, and priorities are captured and included into the drug development and evaluation process.
Contact: patientfocused@fda.hhs.gov.
- **Patient Engagement Advisory Committee (PEAC)**: FDA's Center for Devices and Radiological Health (CDRH) established PEAC to make sure the needs and experiences of patients to receive advice on FDA on complex issues related to medical devices, device regulation and how devices are used.
Contact: CDRHPEAC@fda.hhs.gov.
- **Critical Path Innovation Meetings (CPIM)**: CPIM is a way to discuss methods, technologies, or approaches that may improve and advance the development of drugs through a scientific discussion between FDA staff and stakeholders (e.g., industry, academia, patient advocacy groups, government agencies).
Contact: CPIMInquiries@fda.hhs.gov.