2020 Virtual Advocacy Event

U.S. FOOD & DRUG ADMINISTRATION

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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.

Be Active. Be Heard. Make a Difference.

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U.S. FOOD & DRUG ADMINISTRATION

FDA Patient Affairs Staff

Patients First! How FDA is Making Patients a Priority

Andrea Furia-Helms, MPH
Director, Patient Affairs Staff
Office of Clinical Policy and Programs
Office of the Commissioner

2020 Virtual Advocacy Event

July 2020

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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!

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Evolution of Patient Engagement at the FDA

1988
- Office of AIDS Coordination established

1993
- 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
- First FDA Patient Representative® served on an advisory committee

1996
- FDA Patient Representatives® received voting rights on advisory committees

2001
- FDA Patient Representative Program® role expanded to serve as consultants to scientific and regulatory reviewers

2008
- Patients and consumers encouraged to report medical product problems using FDA's existing MedWatch system

2012
- A section of the FDA website is created specifically For Patients
- Patient-Focused Drug Development (PFDD) initiative launched

2013
- Internal working group examines ways to increase patient involvement in FDA processes
- Consumer-friendly form introduced in FDA's MedWatch system to report medical product problems

2015
- Patient Preference Information (PPI) framework and guidance for medical device decision making
- Patient Engagement Advisory Committee (PEAC) meetings regarding medical devices

2016
- FDA and European Medicines Agency (EMA) Patient Engagement Cluster created
- First Patient Council (internal) meeting held

2017
- PAS established in the Office of the Commissioner
- Public Workshop on PFDD guidance

2018
- Memorandum of Understanding with National Organization For Rare Disorders (NORD) launched the Patient Listening Session pilot program
- Patient Engagement Collaborative (PEC) launched with Clinical Trials Transformation Initiative (CTTI)
- Center for Devices and Radiological Health (CDRH) Patient & Caregiver Connection (P&CC) program launched
- Public Workshops on PFDD guidances and drafts released

2019
- Patient Affairs Staff (PAS) online webform, Patients Ask FDA
- Public Workshop on PFDD
- Draft PFDD guidance released

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Patient Affairs Staff (PAS)

Who we are

What we do

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

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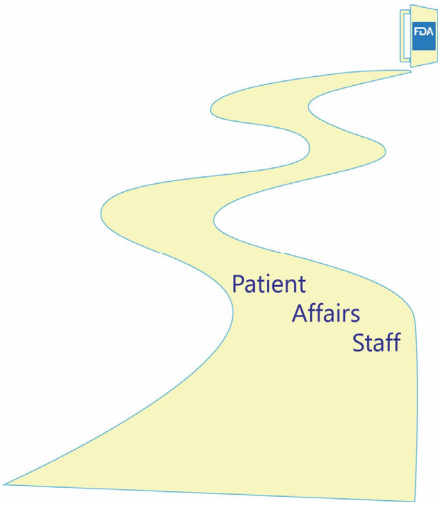
PAS Programs and Activities



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

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FDA and EMA Patient Engagement Cluster

U.S. FOOD & DRUG ADMINISTRATION

FDA

EUROPEAN MEDICINES AGENCY

Mutual exchange on:

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

Publication:
Nature Reviews Drug Discovery 30 September 2019 - *Engaging patients in medicines regulation: a tale of two agencies* https://www.nature.com/articles/d41573-019-00164-y

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CLINICAL TRIALS TRANSFORMATION INITIATIVE

Patient Engagement Collaborative (PEC)

FDA

- 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

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Patient Listening Sessions

Rare Diseases

- 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

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FDA Rare Disease Patient Listening Sessions

Two Types:

1. FDA-requested
2. Patient-requested

Request a Patient Listening Session
www.fda.gov/PatientsAskFDA

Patient Listening Sessions Webpage
www.fda.gov/PatientListeningSessions

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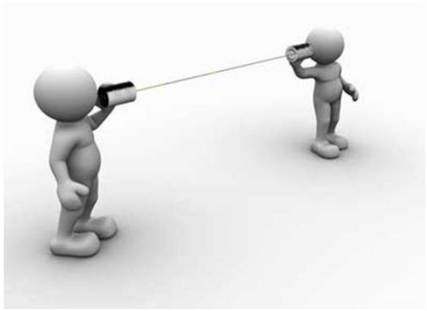
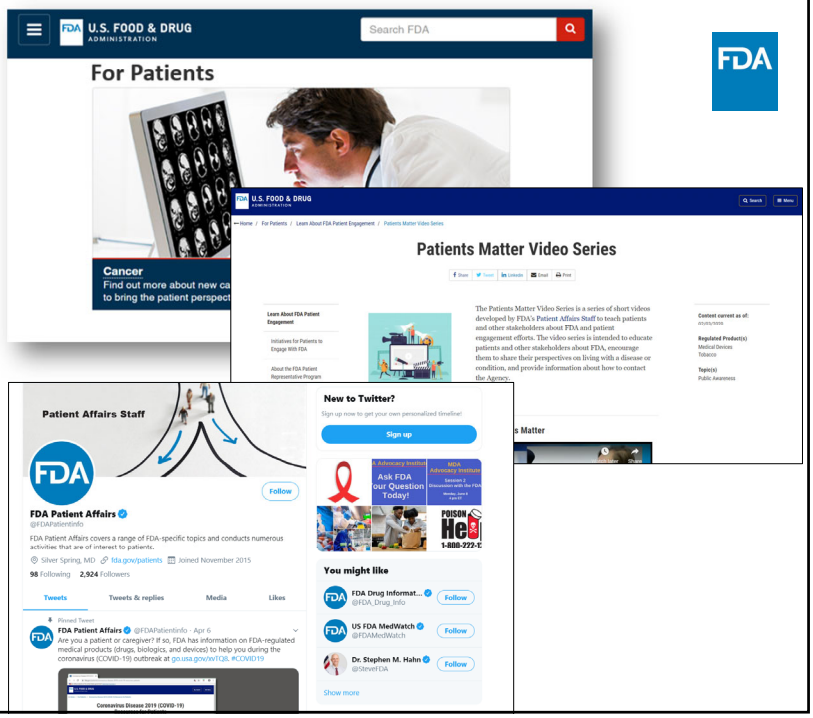
Enhancing Communication with Patients





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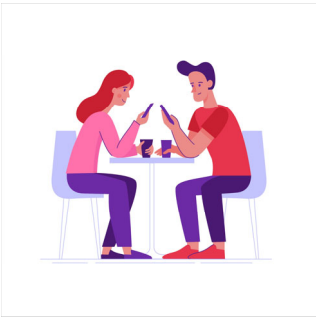
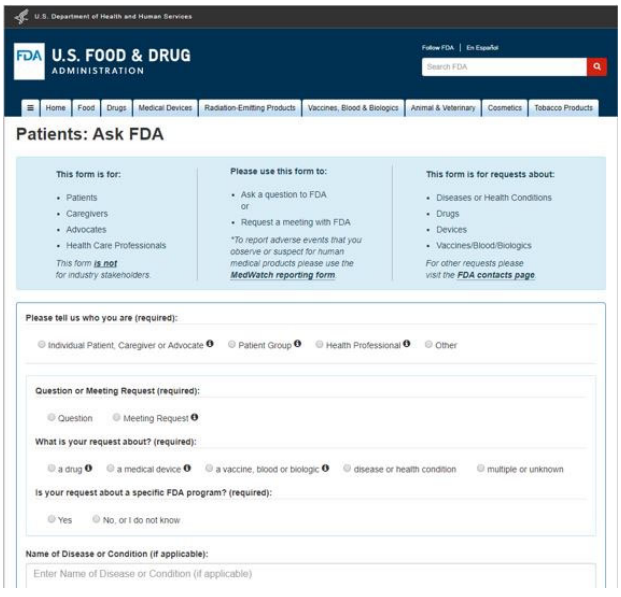
Submit Questions & Meeting Requests





www.fda.gov/**PatientsAskFDA**

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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:

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PATIENT RESOURCES

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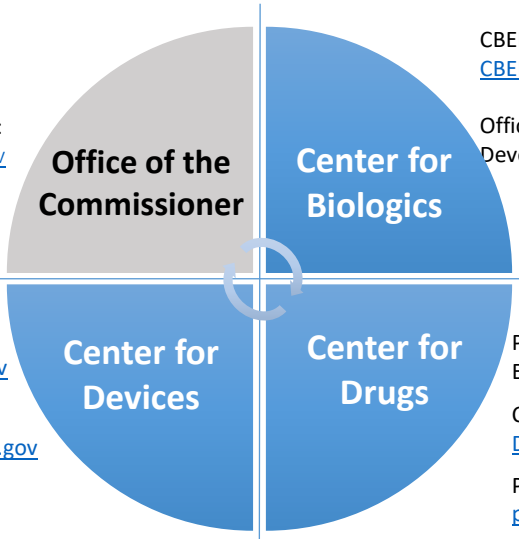
Patient Engagement Contacts Across FDA

FDA Patient Affairs Staff:
PatientAffairs@fda.gov

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



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

Office of Communication, Outreach and Development: OCOD@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

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

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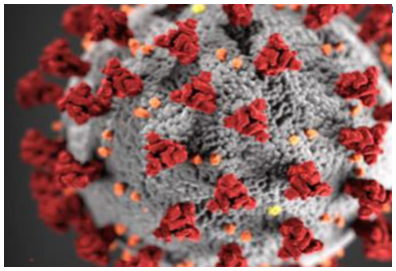
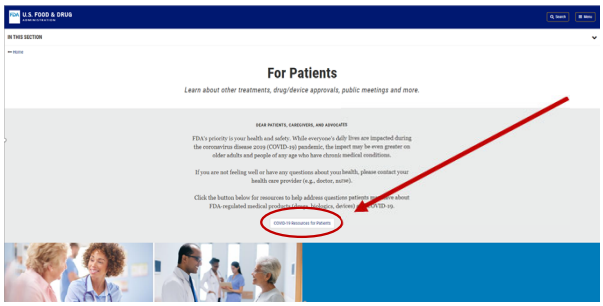


www.fda.gov



www.fda.gov/patients

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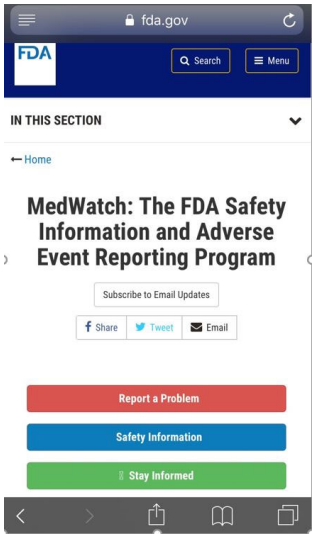
Report Adverse Events to MedWatch



- 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

Acronym	
AC or ADCOM	Advisory Committee
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CTTI	Clinical Trials Transformation Initiative
FDA	U.S. Food and Drug Administration
MOU	Memorandum of Understanding
NORD	National Organization for Rare Disorders
PAS	Patient Affairs Staff
PEAC	Patient Engagement Advisory Committee
PFDD	Patient Focused Drug Development
PPI	Patient Preference Initiative

www.fda.gov

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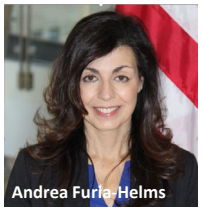
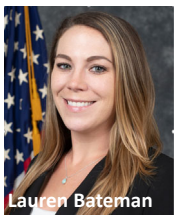
When in doubt…contact Patient Affairs!





PatientAffairs@fda.gov

301-796-8460

www.fda.gov/Patients

@FDAPatientInfo

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