

How to Get Your Voice Heard

FDA Patient Representative Program and Patient Engagement



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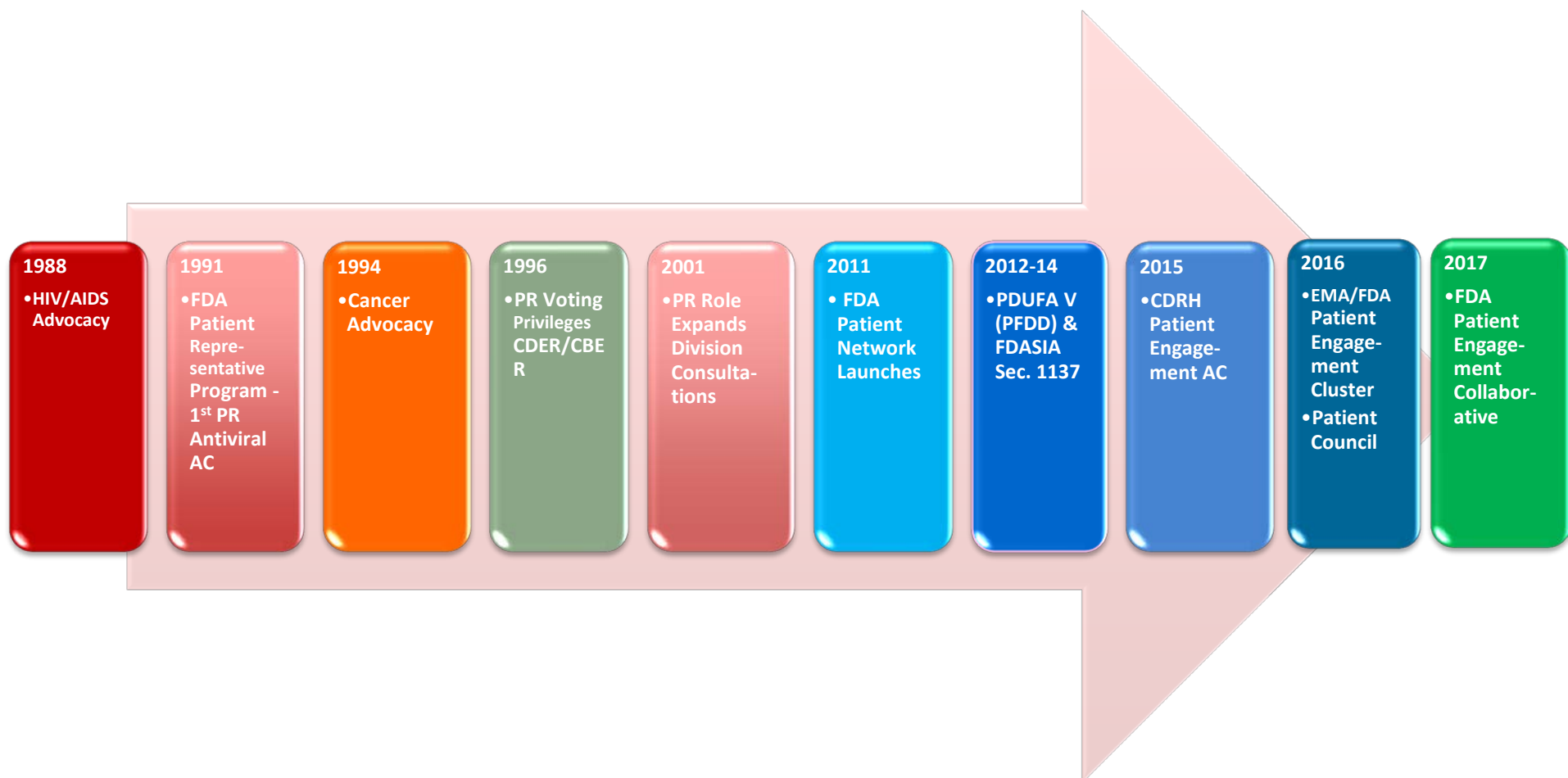
Roadmap for Engaging with CDER
Public Workshop

May 12, 2017

Office of Health and Constituent Affairs

- An office of patient engagement and assistance
- Works across the agency – drugs, devices and biologics
- Advocates within the agency for patients
- Working to include patient voices in regulatory activities and decision-making

FDA Patient Involvement Milestones



FDA Patient Representative Program

- Began in 1990s
- Patients having an active role on FDA Advisory Committees and in review division consultation meetings
- Patient voice represented in important discussions about regulatory decision-making
- Presence at the table



Who are Patient Representatives?

- Patients with a disease/condition
- Primary caregivers to patients (i.e., spouse, parent, family member)
- Members of patient/community advocacy groups



FDA Patient Representative Program

- Special Government Employees (SGEs)
- Access to confidential background information
- Over 200 patients and caregivers
- Over 300 diseases and conditions



Recruitment and Preparation

Recruitment

- Based on need
 - Products in development
 - Product applications at FDA for review

Preparation/Training

- Webinars
- Annual workshop
- Mentoring by senior patient representatives
- One-on-one support as needed

Furtheres an understanding and appreciation for FDA's role in medical product development, review and patient protection.

Broadening Patient Input

FDASIA Section 1137

- FDA Safety and Innovation Act (FDASIA) 2012
- Sec. 1137: Patient participation in medical product discussions
- Develop ways to include patients earlier in medical product development



FDASIA 1137

What has been done so far?

- Cross-Agency work group formed
- Docket opened for public comment
- A Stakeholder Views summary report of comments received
- Ongoing
 - Centers implementing patient engagement activities
 - Cross-Agency work group evolved into Patient Council

New Patient Engagement Initiative

Coming Soon



www.fda.gov/forpatients

Patient Engagement Collaborative (PEC)

- External stakeholder group for ongoing discussions about enhancing patient participation in regulatory processes and policy development across the medical product Centers.
- A forum to exchange information, ideas and experiences on general matters of interest to patients/patient advocates related to patient engagement at FDA.
- Leveraged CTTI's patient advocate steering committee members to help develop the framework for the PEC
- Part of FDASIA Section 1137 and the FDA's continued commitment to raising greater patient involvement and input in FDA decisions

How to Get Your Voice Heard

Moderator:

Rea Blakey

*Communications Policy Strategist & Engagement Team Lead,
Professional Affairs and Stakeholder Engagement (PASE)*

Panelists:

- **Andrea Furia-Helms, M.P.H.,** *Health Programs Coordinator, Office of Health and Constituent Affairs (OHCA)*
- **Christopher Melton,** *Health Communications Specialist, Professional Affairs and Stakeholder Engagement (PASE)*
- **Pujita Vaidya, M.P.H.,** *Acting Director, Decision Support and Analysis Team, Office of Strategic Programs (OSP)*
- **Lynne P. Yao, M.D.,** *Director, Division of Pediatric and Maternal Health*

