How to Get Your Voice Heard

FDA Patient Representative Program and Patient Engagement

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Roadmap for Engaging with CDER
Public Workshop

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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 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

Furthers 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
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
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Moderator:
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Panelists:
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• 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