CBER Patient Engagement

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CDER and You: Keys to Effective Engagement Workshop

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U.S. FOOD & DRUG ADMINISTRATION

Disclaimer

My comments are an informal communication and represent my own best judgment. These comments do not bind or obligate FDA.

CBER AND PATIENT ENGAGEMENT

Dr. Peter Marks, Director, CBER, (front row, fourth from left)), and CBER staff gathered in the atrium of Building 71 at the White Oak Campus, Silver Spring, MD, on December 5, 2017, for this photo.

INTRODUCTION TO THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

We are Listening

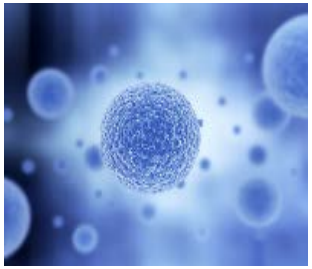
- Patients provide an important and unique perspective that is critical for consideration as part of the regulatory process
- We highly value patient engagement and its contribution to the development of biological products

Patient-Focused Product Development

- Evolving:
  - FDASIA, FDAMA, 21st Century Cures Act
- Sections 3001-3004 of the Cures Act
  - Patient Experience Data as part of a marketing application
  - Issuance of guidance documents addressing methodological approaches to collecting, analyzing, and submitting patient experience data
  - FDA to publish a report on patient experience data

https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM563618.pdf.

Products Regulated by CBER



- Vaccines (preventative and therapeutic)
- Allergenics
- Live Biotherapeutic Products
- Blood Products
- Devices Related to Biologics
- Human Tissues and Cellular Products
- Xenotransplantation Products
- Gene Therapies

Types of CBER Meetings with Patient Involvement – Product Specific

- With Product Office/Review Team
  - Investigational Stage
  - May include IND Sponsor
- Advisory Committee Meetings
  - For specific issues during development
  - During BLA review

Types of CBER Meetings with Patient Involvement – Issue or Disease Specific

Advisory Committee Meetings

Public Meetings/Workshops

- Topics facilitate product development & regulation
- Usually collaborate with organizations & other agencies

Meetings with Patient Organizations

Patient Focused Drug Development Meetings

- Internally led
- Externally led

Contact Information

- **CBER website:**

  www.fda.gov/BiologicsBloodVaccines/default.htm
- **Phone:** 1-800-835-4709 or 240-402-8010
- **Consumer Affairs Branch**: ocod@fda.hhs.gov
- **Manufacturers Assistance and Technical Training Branch**: industry.biologics@fda.hhs.gov
- **Follow us on Twitter:** https://www.twitter.com/fdacber