FDA Patient Representative Program

- Began in 1990s and evolved.
- Patients having an active role on FDA Advisory Committees and in consultations with review divisions.
- Patient voice represented in important discussions about regulatory decision-making.
- Furthers an understanding and appreciation for FDA’s role in medical product development, review and patient protection.
- Presence at the table.
Experiences Represented

200 FDA Patient Representatives
300-500 diseases/conditions/device experiences

- AIDS/HIV
- Alzheimer’s Disease
- Asthma
- Cancer (various)
- Cardiovascular disease
- Cerebral Palsy
- Crohn's disease
- Cystic Fibrosis
- Duchenne Muscular Dystrophy
- Diabetes
- Diabetes (insulin pumps)
- Fabry Disease
- Hepatitis B
- Hepatitis C

- Infantile Spasms
- Lung Transplantation
- Lupus
- Lysosomal Acid Lypase Deficiency
- Major Depressive Disorder
- Muscular Dystrophy
- Obesity/Weight Control
- Opioid Use
- Parkinson's Disease
- Pompe Disease
- Sickle Cell Disease
- Short Bowel Syndrome
- Temporomandibular joint disorder
- Transplantation
Becoming an FDA Patient Representative

• Personal experience with the disease or condition as either a patient or primary care giver.

• Patient community awareness: active in patient advocacy organizations, knowledgeable about treatment options and research, other advocacy activities.

• Someone who is analytical and objective, doesn’t need to be a scientist but should grasp scientific principles and understand issues, experienced with decision making based upon complex information.

• Minimal or no conflict of interest.

• Good communications skills.

• Commitment to serve.
Where Patient Reps Intersect with Drug/Biologic Development?

- Basic Research/Discovery
  - Translational
  - Pre-IND
  - Clinical
  - NDA/BLA Review
  - Post-marketing

Drug Developers

Patient Reps serve as Consultations (divisional assignments)

Patient Reps serve on FDA Advisory Committees
FDA Patient Representatives on Advisory Committee Meeting Panels

• Temporary voting members.
• Screened for each assignment.
• Other disciplines at the table.
• Across all medical product Centers.
• 40-60 assignments/year.
FDA Patient Representatives also serve...

...as consultants with review divisions:

- Brings the voice earlier in the regulatory process.
- Divisional “homework” assignments.
- Consult directly with scientific review staff and sponsor
- Closed meeting (telecon).

...at workshops

...on symposiums
We Train and Prepare for Service!!!

• Describe significance of program
• Describe FDA regulatory framework and decision-making process (FDA 101)
• Share experiences: internal and peer
• Describe scenarios for the meeting
• Offer regular webinars (training modules)
• Provide online resources for patients
• Host Annual Patient Representative Workshop
FDA Patient Representative Program
2017 Training Workshop Cohort