

# FDA Patient Representatives and FDA Consumer Representatives, an OSHI Perspective

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FDA Office of Special Health Issues

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Work with patients and their advocates to encourage and support their active participation in FDA decision-making and policy formulation.

# Background, FDA Patient Representative Program

- Patients wanted a more active role in FDA regulation of medical products
- Antiviral Drugs Advisory Committee, February 13-14, 1991
- FDA Patient Consultant Program, 2001
- Combining the two programs into a single FDA Patient Representative Program

# FDA Patient Representatives

- Not technical experts
- Experts on a serious or life-threatening disease
- Bringing the voice of the patient to FDA

# Serious and Life-threatening Diseases

- AIDS/HIV
- Alzheimer's Disease
- Asthma
- Cancer
- Cardiovascular disease
- Cerebral Palsy
- Chronic pain
- Crohn's disease
- Depression
- Diabetes
- Fibromyalgia

- Hepatitis B & C
- Irritable Bowel Syndrome
- Lung Transplantation
- Lupus
- Macular Degeneration
- Major Depressive Disorder
- MRSA
- Neuropathy
- Obesity/Weight Control
- Parkinson's Disease
- Polio
- Sickle Cell Disease
- Short Bowel Syndrome
- TMJ

# Selection Criteria

- Personal experience with the disease
- Experience with available treatments for that disease
- Exposure to others with that disease
- Knowledge of their general needs and preferences

# Additional Selection Criteria

- Advocacy experience
- Interest in learning about scientific & FDA processes and standards
- No need for training in a health care-related field, but experience with complex decision-making is helpful
- No “agenda” other than serving patients
- Conflict-of-interest clearance

# Administered by the FDA Office of Special Health Issues

- OSHI Patient Liaison Program
- Recruitment
- Selection with FDA review divisions
- Training and development
- Identification of opportunities to serve
- <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/PatientInvolvement/default.htm>

# Recruitment

- National patient advocacy organizations
- Regional or local organizations
- Health care providers
- Self-nominations
- Web searches
- Other sources
- Importance of conflicts of interest

# Initial and Ongoing Training

- Orientation
- The role of the patient representative
- Medical product development
- FDA regulation of development and marketing
- Safety of marketed products
- Human subject protection
- Interpretation of clinical data

# Initial and Ongoing Training (cont.)

- Dealing with potential conflict-of-interest situations
- Dealing with the press
- Maintaining objectivity while engaging as an advocate

# **Patient Representative Contributions to Deliberations**

- Trial Design
- Drug Toxicity Issues
- Quality of Life Issues
- Study Recruitment
- Informed Consent
- Expanded Access
- Product Labeling

# Consumer Protection

- Progressive Era, President T. Roosevelt
- U.S Food and Drug Administration, 1906  
Pure Food and Drugs Act
- U.S. Federal Trade Commission (1914),  
“unfair and deceptive acts or practices”
- Ralph Nader, Unsafe at Any Speed  
(1965)
- Consumer Federation of America (1968)

# Consumer Protection (cont.)

- Occupational Safety and Health Administration (1970), workplace safety
- Consumer Product Safety Commission (1972), “...protecting the public from unreasonable risks of serious injury or death from thousands of types of consumer products”
- Tension between consumer protection and deregulation

# Other Consumer Protections

- “Do Not Call” registry
- Protections against identity theft
- Regulation of professions
- Loan and credit card laws
- Contractor, zoning laws
- Utilities regulation
- 2010 Health reform law?

# FDA Consumer Representatives

- Ties to consumer and community-based organizations
- Able to analyze technical data
- Understand research design
- Able to discuss benefits and risks
- Able to evaluate the safety and efficacy of products under review.

# How do Consumer Representatives Contribute?

- Represent the consumer perspective on issues and actions before the advisory committee
- Serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations
- Facilitate dialogue with the advisory committees on scientific issues that affect consumers.

# Distinctions between FDA Patient Reps and Consumer Reps

- Patient Representatives can address specific needs and preferences of patients for whom the treatment is intended
- Consumer Representatives offer broader knowledge of consumer rights and needs

# Overlapping Capacities to Contribute

- Protection from deception
- Facilitating full, objective communication
- Protection from injury

# Shared Goals

- Broader stakeholder involvement in FDA decision making
- More-rational FDA risk/benefit decisions
- Legitimizing FDA processes and decisions by involving those most affected

Thank you!

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