

Patient Engagement at the FDA and NIH

Patient Advocacy Workshop
November 14, 2015



FDA Engagement Options

- Oral public comments
- Written comments
- Representative on FDA advisory committee



FDA: Finding Opportunities

- FDA Patient Network:
<http://www.fda.gov/ForPatients/default.htm>
- Federal Register: <http://www.gpo.gov/fdsys/>
- Patient Representative:
<http://www.fda.gov/ForPatients/About/ucm412709.htm>



FDA: Oral Public Comments



- Email contact in Federal Register to request to speak
 - Note deadline in Federal Register
- For advisory committee meetings
 - Review background materials posted online 48 hours prior to meeting

FDA: Oral Testimony Tips

- Be clear and concise
- Be sure your comments fit within your time limit
- Focus on 2 – 3 main points
- Use plain language
- Avoid the temptation to speak too fast



FDA: Components of Effective Testimony

- Introduction
- State your position
- State your concerns
- State your recommendation



FDA: Submitting Written Comments

- Follow the same principles for good oral comments
 - Be clear and concise
 - Focus on 2-3 main points
 - Use plain language
 - Include an introduction, state your position, state your concerns, make your recommendation
- Website: <http://www.fda.gov/ForPatients/default.htm> or <http://www.regulations.gov/#!/home>



FDA: Role of the Patient Representative

- Offer the patient's perspective
- Provide your recommendations and thoughts
- Vote on the decision at hand (if you are a voting member)



FDA: Patient Representative Requirements

You must be a U.S. citizen and at least 18 years old and have:

- Personal experience with the disease either as a patient, or caregiver for a family member or friend
- Ability to be objective while representing the concerns of other patients
- Knowledge about treatment options for the disease and research in that area
- Willingness to communicate your views
- No financial or ethical conflicts of interest for self or close family member



FDA: Where to Find Patient Representative Information and Openings

Find vacancies:

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/AdvisoryCommitteeVacancies/default.htm>

Patient Representative:

<http://www.fda.gov/ForPatients/About/ucm412709.htm>



FDA: How to Apply to be a Patient Representative

Your application should include:

- Your personal experience with a disease
- Why you are interested in becoming a Patient Representative
- Any **advocacy** work you have done
- Work and/or volunteer experience you've done related to the specific disease area
- Information about your ability to represent patients and communicate their perspectives



Email your application to: PatientRepProgram@fda.hhs.gov



Join the Conversation

NIH: Opportunities for Patient Engagement

NIH

National Institutes of Health
Turning Discovery Into Health

NIH: National Heart, Lung, and Blood Institute (NHLBI)

<http://www.nhlbi.nih.gov/files/docs/public/nhlbi-listens.pdf>

FROM PUBLIC ADVOCACY



TO RESEARCH PRIORITIES

NHLBI LISTENS AND RESPONDS

NHLBI: Collaboration with Advocacy Groups



And many
others!




Email for more information:
NIHinfo@od.nih.gov



NIH National Cancer Institute: Office of Advocacy Relations

<http://www.cancer.gov/about-nci/organization/oar>



1-800-4-CANCER Live Chat Dictionary

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About the NCI Council of Research Advocates

About OAR +



Office of Advocacy Relations

The NCI Office of Advocacy Relations (OAR) engages cancer research advocates and serves as a link for advocate stakeholders to collaborate with NCI. OAR works with individual research advocates, local and

Latest for Advocates

NCI: Research Advocacy Process

Advise

Design

Review

Disseminate

NCI Research Advocate Requirements

- At least 2 years of involvement with cancer research-related activities
- Personal experience with cancer
- Ability to express a “collective patient perspective”
- Residency in the United States
- Fluency in English



Become an NCI Research Advocate

- Create
- Select
- Prepare
- Participate
- Evaluate





"Consumer advocates are playing such an important role with their support of cancer research. They are providing critical analyses and insights that help ensure that research advances are more quickly and carefully translated to the patient and public health settings."

**- Dr. Christopher L. Hatch,
Chief, Program Coordination
and Referral Branch Division of Extramural Activities**

NCI Office of Advocacy Relations

Phone: 301-594-3194

Email: NCIadvocacy@nih.gov

Web: www.advocacy.cancer.gov



Questions?



Phone: (202) 223-4000

Paul Brown: pb@center4research.org

Tracy Rupp: tr@center4research.org

Testimony Examples

1. Kate Marshall - Orkambi

START AT 1:18 MINUTE MARK (FULL VIDEO IS 4:18)

https://www.youtube.com/watch?v=3ARdU_FVAgA

2. Jamie Tierney – antidepressants

START AT 0:29

<https://www.youtube.com/watch?v=Uhec-FDVEW4>

3. Patient – lorcaserin

START AT 3:28 AND STOP AT 6:06

<https://www.youtube.com/watch?v=vih0pxY23lY>