

LBCA Advocate Chat Series 2021

Advocacy Opportunities at the Federal Level



lobularbreastcancer.org

Welcome and Today's Session

Information about today's session:

- Presentation portion will be recorded, and all participants will be muted
- Question and Answer period, which will not be recorded, will follow:
 - Write your questions in the chat throughout the presentation
 - During the Q & A portion, questions from the chat will be read. The moderator may call on people as well who indicate in the chat that they would like to ask a question
 - **NOTE:** Please avoid any questions about personal issues or specific medical questions as they can not be addressed during this event



Advocacy Opportunities at the Federal Level

Breeze Riley

National Cancer Institute (NCI)

Office of Advocacy Relations



Salina Miller

U.S. Food and Drug Administration (FDA)

FDA Patient Representative Program®



lobularbreastcancer.org

Advocate Engagement at NCI

*Breeze Riley, Advocacy Relations Manager
NCI's Office of Advocacy Relations*

The National Cancer Program

As the leader of the National Cancer Program, NCI:

- conducts and supports research and training
- disseminates health information
- manages programs with respect to understanding the cause, diagnosis, prevention, treatment of cancer, and the continuing care of cancer patients.



NCI's Work

NATIONAL CANCER INSTITUTE SCOPE OF OUR WORK



Executing NCI's Mission

Intramural Research Program (IRP)

Scientists, physicians, and clinicians who conduct basic, clinical, and genomic and population-based research at the NIH Clinical Center and NCI offices and laboratories in Maryland.

Includes the Center for Cancer Research and the Division of Cancer Epidemiology and Genetics.

Extramural Research Program (ERP)

Non-government scientists in laboratories and clinical facilities throughout the country.

80% of NCI funding goes towards research proposed and conducted by the ERP.

Includes the Division of Cancer Biology, Division of Cancer Control and Population Sciences, Division of Cancer Prevention, Division of Cancer Treatment and Diagnosis and Division of Extramural Activities.

“Advocates’ dedication to cancer research and improving outcomes for patients helps make the work of the NCI and its investigators possible. I commend all of them for their passion and commitment.”

-Dr. Norman Sharpless, NCI Director



Office of Advocacy Relations (OAR)

NCI's 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 national advocacy groups, and professional societies to ensure the collective patient perspective is included in NCI efforts to advance cancer research and improve patient outcomes.



NATIONAL CANCER INSTITUTE
Office of Advocacy Relations

What We Do

As part of NCI's Office of the Director, OAR coordinates engagement across the cancer research advocacy community **to improve understanding, opportunity, and progress in cancer research.**



Communicate



Facilitate



Collaborate

How We Work With Program Staff

- OAR works with program staff across the NCI to:
 - consult on how advocates can be effectively integrated into new or existing NCI programs and initiatives
 - work with program staff if any specific concerns arise surrounding a particular advocate engagement or activity
 - field any advocate inquiries redirected from program staff
 - advise program staff on issues important to the advocacy community

Collaborating with the Advocacy Community

OAR works with individual research advocates by:

- serving as a conduit between the cancer advocacy community and NCI research and program staff
- recommending creative solutions for advocate engagement at NCI
- vetting and recruiting trained advocates for NCI opportunities
- ensuring advocates are positioned for success and prepared to add value to NCI's work

ADVISORY BOARDS • MATERIALS REVIEW • PLANNING COMMITTEES
PEER REVIEW • STEERING COMMITTEES • USABILITY TESTING • AND MORE!



Office of Advocacy Relations
Learn more at advocacy.cancer.gov

Who We Talk to in the Advocacy Community

Two-way communication with OAR's network of advocates and advocacy organizations is vital in maintaining the culture of advocate engagement at NCI. Our audience includes:

Individual Research Advocates

- OAR manages a network of **259** active advocates spanning cancer types and geographic regions.
- **7** of these advocates were new in 2020.

Advocacy Organizations

- OAR works with advocacy organizations **ranging in size and focus** including organizations focused on a specific cancer type, coalitions, and survivorship groups.

Growing a Network of Advocates

One of the ways in which OAR supports a culture of advocate engagement is by referring advocates to programs and activities across the NCI.

Those referrals often come from an existing network of **more than 250+** active advocates spanning cancer types and geographic regions.

- In 2020, OAR referred **57** advocates for activities at NCI. In addition, we continued to collaborate with our external colleagues in the National Cancer Program by connecting them with advocates upon request.
- Examples of NCI activities include:
 - *Steering committees/Advisory committees*
 - *NCI Council of Research Advocates (NCRA)*
 - *Peer review*
 - *Speaking engagements*
 - *Workshops*

Connecting Advocates with NCI

Keeping advocates engaged requires a mix of proactively communicating NCI's priorities and initiatives to the community and responding to inquiries and concerns from advocates and organizations.

- **Phone Calls** – The OAR office fields regular calls with advocates or organizations to discuss issues relevant to NCI.
- **News digest/ Listserv notices** – OAR maintains a listserv with **1,068** subscribers. In addition to receiving timely email announcements and event invitations they also receive a **monthly digest** updating them on the latest NCI news, events, and research.
- **Webinars** – **Orientation webinars** are held to onboard new advocates, while topic-specific webinars are held to educate advocates on a broad range of topics.
- **Meetings** – OAR convenes meetings with advocates and NCI staff throughout the year to make sure the collective patient perspective is heard.

Profile of a NCI Research Advocate

- **Personal experience** from one's own diagnosis, or has connection to someone diagnosed with cancer
- **Affiliated with a cancer research organization** (academia, nonprofit)
- **Prior involvement** in cancer research advocacy or advocacy training
- Ability to convey a **collective patient perspective** over one's own exclusive disease experience
- Comfort **interacting with diverse audiences and teams**, while **engaging in scientific discussions** and reviewing scientific material

NCI Opportunities for Advocate Engagement



Case Study:

PS-ON (Physical Sciences Oncology Network) Patient Advocacy Working Group

- Participate in bi-monthly teleconferences to share information and best practices across centers, discussing opportunities, challenges, and successes.
- Engage as a member of the research team, contributing to dissemination, translation, and outreach and education efforts.
- **Contributions**
 - Advocates participated in the 2020 virtual annual PS-ON Meeting
 - Served on planning committee
 - Served as poster judges
 - Presented patient stories
 - Facilitated break-out sessions
 - Recorded advocate “spotlights”
 - Contributed to program mission statements from the patient perspective
 - Engaged in community outreach through funded projects and centers, collaborating with NCI-funded researchers
 - Worked with junior investigators on plain language improvements to their research presentations

Thank you!

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FDA Patient Representative Program[®]

Salina Miller, M.S., M.B.A.






Manager, FDA Patient Representative Program[®]

Advisory Committee Oversight and Management Staff (ACOMS)
Office of the Commissioner



FDA Patient Representative Program[®]

Presentation Agenda

I	II	III	IV	V
FDA and Patient Engagement	FDA Patient Representative Program [®]	Recruitment	Criteria	Contact
				

FDA and Patient Engagement

How did it all start?

- Late 1980s: HIV/AIDS crisis.
- Patients wanted a more active role in FDA regulation of medical products.
- First Patient Representative Serves: Antiviral Drugs Advisory Committee, Feb. 13-14, 1991.
- 1991: FDA Patient Representative Program formed.



Learn more on the [Evolution of Patient Engagement at FDA](#)

Patient Engagement Opportunities at FDA



FDA-led Patient-Focused Drug Development (PFDD)
NORD MOU Pilot Rare Disease Listening Sessions
Patient Engagement Collaborative (PEC)
Patient Engagement Advisory Committee (PEAC)
Patient & Caregiver Connection (PCC)
FDA Patient Representative Program[®]

Learn more at [FDA Patient Engagement Opportunities](#)

FDA Patient Representative Program®

What is the FDA Patient Representative Program?

FDA's flagship program aimed at including patient perspectives to the Agency's decision-making process as it regulates medical products (drugs, biologics, and medical devices).

Special (or Regular) Government Employees
Access to confidential and proprietary information



FDA Patient Representative Program®

PRIMARY: Serve on FDA Advisory Committees

- A panel of outside experts convened periodically to advise the FDA on safety and efficacy issues about regulated medical products.
- 31 Advisory Committees; Medical Devices Advisory Committee (18 panels)
- Committee/Panel members include:
 - Committee Chair
 - Medical Experts & Specialists
 - Statisticians
 - Consumer Representative
 - Industry Representative
 - FDA Patient Representative®

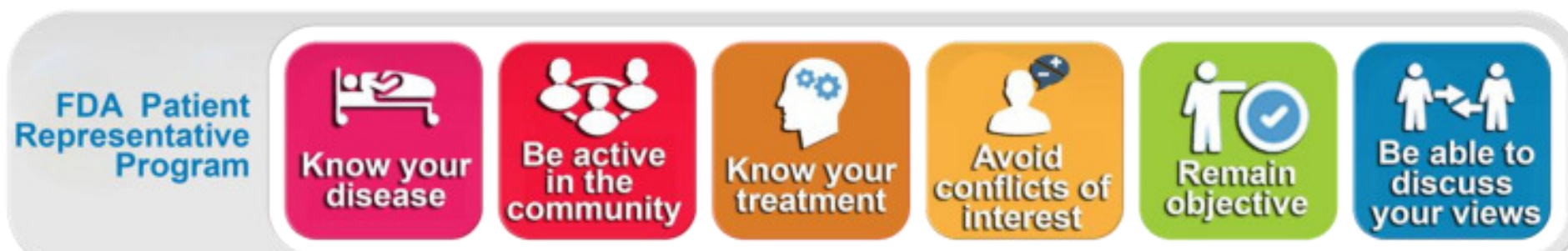


View upcoming meetings at [FDA Advisory Committee Calendar](#)

FDA Patient Representative Program[®]

SECONDARY: Consult with Agency's Clinical Review Team

- Brings the patient voice to discussions earlier in the regulatory process
- Consult directly with clinical review staff and sponsors
- Access to confidential information from the sponsor/company
- Closed/confidential teleconference



FDA Patient Representative Program[®]

Disease, Condition, Drug & Medical Device Experiences Represented in Program

- AIDS/HIV
- Alzheimer's Disease
- Asthma
- Breast implants
- Cancers--including: *metastatic breast cancer, non-metastatic breast cancer, metastatic small cell lung cancer, metastatic non-small cell lung cancer, colon cancer, brain tumors, rare cancers, renal cell carcinoma, neuroendocrine tumors, leukemia, ovarian, multiple myeloma, pancreatic cancer, pediatric cancers*
- Diabetes
- Duchenne Muscular Dystrophy
- Fabry Disease
- Fibrodysplasia ossificans progressiva
- Infantile Spasms
- Inborn Errors
- Lysosomal Acid Lypase Deficiency
- Major Depressive Disorder
- Muscular Dystrophy
- Nicotine Replacement Therapy
- Opioid Use
- Organ transplantation
- Parkinson's Disease
- Pompe Disease
- Prader-Willi Syndrome
- Schizophrenia
- Short Bowel Syndrome
- Sickle Cell Disease

FDA Patient Representative Program®

How Do We Recruit?

- National Patient Advocacy Organizations
- Regional or Local Organizations
- Rare Disease Groups
- Health Care Providers
- FDA Centers and Divisions
- Other Federal Agencies
- Leads from Agency-Sponsored Activities
- Self-Nominations
- Other FDA Patient Representatives
- Web, Email, Social Media

Recruitment is driven by
AGENCY NEED!

Currently recruiting for:
metastatic breast cancer
non-metastatic breast cancer





FDA Patient Representative Program®

What's the CRITERIA?

- Personal experience with a disease, condition or device (self or caregiver).
- Must be 18 years or older (or represented by parent/caregiver).
- Must be either a US citizen or greencard holder.
- Active and engaged within your community.
- Knowledgeable about treatment options and research.
- Basic knowledge of regulatory science and terminology.
- Good communications skills.
- Committed to service.

FDA is committed to increasing the diversity of racial, ethnic, and gender minorities and enhance participation of underrepresented demographic subgroups.

Candidates representing these groups are highly encouraged to apply.

(Learn more on [FDA's Oncology Center of Excellence's Project Equity](#))

FDA Patient Representative Program[®]

What's the CRITERIA? con't...

- Impartial with minimal-to-no conflicts of interest (financial or ethical) for self or close family members. Considerations include:
 - Financial interests (stocks, etc.) in companies that may be affected by FDA decisions
 - Formal positions within an advocacy organization (volunteer or paid)
 - Funding/financial support of advocacy activities
 - Activities with ties to pharmaceutical or medical device companies—advocacy or professional work
 - Participation in clinical trials relevant to the meeting topic
 - Ties to Contract Research Organizations (CROs) and Institutional Review Boards (IRBs)
 - Grant or contract review work

FDA Patient Representative Program®

We Train and Prepare

- Describe significance of program
- Describe FDA regulatory framework and decision-making process (FDA 101)
- Share experiences: internal and peer
- Describe scenarios for the meeting
- Provide online resources for patients
- Share info on agency activities



FDA Patient Representative Program®

When a Patient Speaks: Testimonials from FDA Patient Representatives



Gigi McMillan, FDA Patient Representative®

FDA Patient Representatives bring the non-scientific points of view that are from their real-world experience.

Watch Gigi's testimonial, along with those from other FDA Patient Representatives, at
<https://www.fda.gov/patients/learn-about-fda-patient-engagement/when-patient-speaks-testimonials-fda-patient-representatives>

FDA Patient Representative Program[®]

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Follow **@US_FDA** on Twitter

Learn more about the [FDA Patient Representative Program[®]](#)



Thank you!



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Questions & Answers