AACR American Association for Cancer Research

FINDING CURES TOGETHER℠

PARTNERS IN PROGRESS: CANCER PATIENT ADVOCATES AND THE FDA

A Workshop Sponsored by the FDA's Oncology Center of Excellence, with Support from AACR, ASCO, and ASH
November 13, 2017

Jon G. Retzlaff, MBA, MPA
Chief Policy Officer
Vice President, Science Policy and Government Affairs

MY PRESENTATION TODAY

American Association for Cancer Research
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- Present an overview of the AACR
- Discuss how the AACR is working with advocates to accelerate progress and address the challenges in the field
- Summarize how patient advocates are playing a crucial role in our ongoing collaborative efforts to prevent and cure cancer.

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AACR VISION AND MISSION

American Association for Cancer Research
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To be the most effective catalyst for the cures and prevention of all cancers through:

- Research
- Education
- Communication
- Collaborations
- Funding for cancer research
- Advocacy

Founded 110 years ago, the AACR is the first and now the largest cancer research organization in the world dedicated to the conquest of cancer

BACKGROUND RE: THE AACR

AACR American Association for Cancer Research
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- AACR membership includes more than 37,000 laboratory, translational, and clinical researchers; population scientists; other health care professionals; and patient advocates residing in 108 countries.
- AACR annually convenes more than 30 conferences and educational workshops, the largest of which is the AACR Annual Meeting with more than 21,900 attendees.
- AACR publishes eight prestigious, peer-reviewed scientific journals and a magazine for cancer survivors, patients, and their caregivers.
- AACR funds meritorious research directly as well as in cooperation with numerous cancer organizations, including serving as the Scientific Partner of Stand Up To Cancer.
- AACR actively communicates with legislators and other policymakers about the value of cancer research and related biomedical science in saving lives from cancer.

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KNOWLEDGE IS POWER!
AACR CANCER PROGRESS REPORT SERIES

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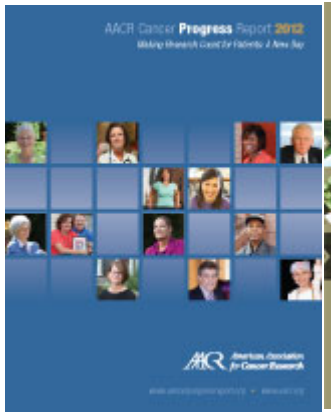

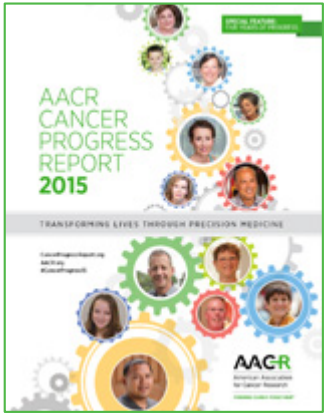

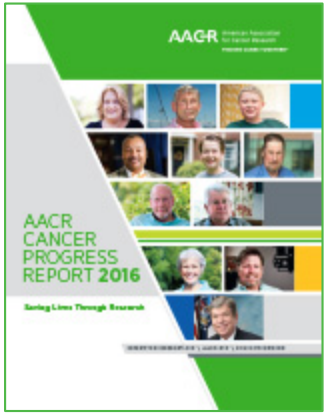

- The AACR Cancer Progress Report captures progress against cancer in a given year
- Emphasizes how progress is benefiting cancer patients
- Its principal goals are: scientific communication, education, and advocacy
- The seventh edition was released in Washington, DC on September 13, 2017
- www.CancerProgressReport.org

AACR CANCER PROGRESS REPORT 2017

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RECENT PROGRESS IN THE CLINIC AGAINST CANCER

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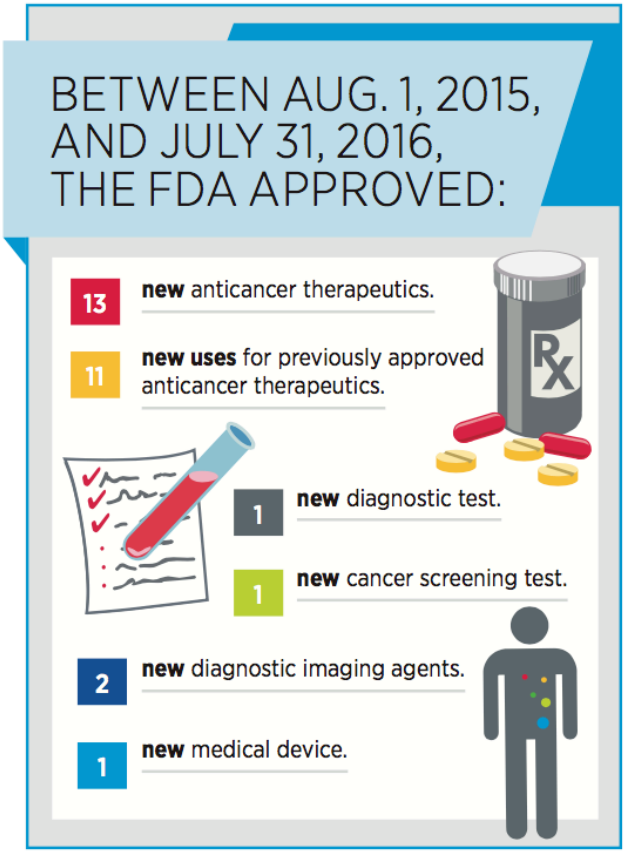

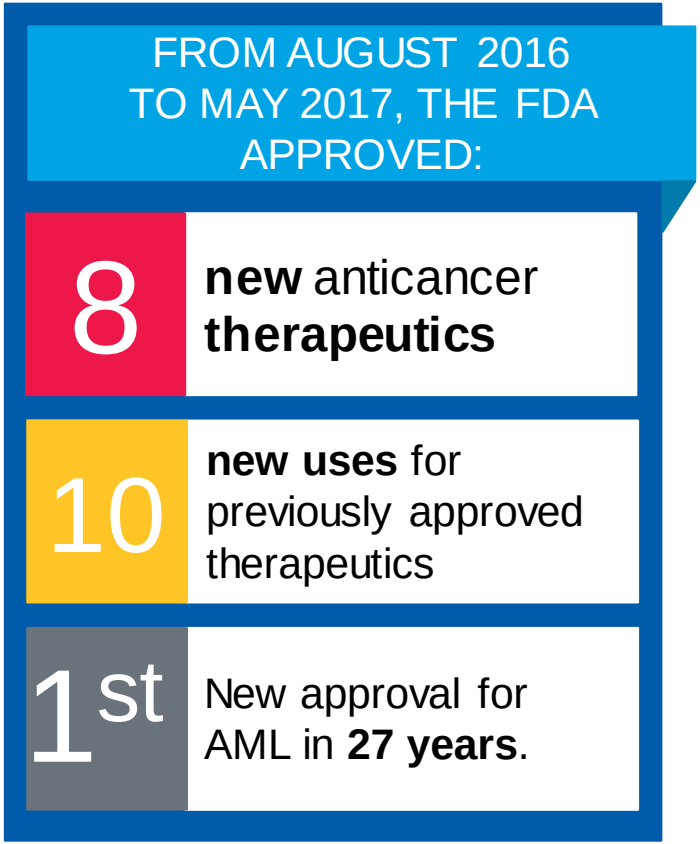

American Association for Cancer Research Cancer Progress Report 2016

RESEARCH CONTINUES TO POWER MOLECULARLY TARGETED THERAPY

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- Leading to the FDA approval of new therapeutics, including:
  - A new PARP inhibitor, **niraparib**, for treating patients with advanced ovarian cancer, like **Teri Woodhull**

  - A PDGFRA-targeted therapeutic, **olaratumab**, which is benefitting patients with soft tissue sarcoma, like **Evan Freiberg**

RESEARCH CONTINUES TO ADVANCE IMMUNOTHERAPY

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Leading to new and expanded uses of **checkpoint inhibitors**:

- **Pembrolizumab**, for treating patients like Adrienne Skinner, based on their tumor's genetic characteristics, rather than site of origin.
- **Pembrolizumab**, for treating patients with head and neck cancer, like Bill McCone.
- **Avelumab**, as the first ever treatment option for patients with Merkel cell carcinoma, like Carrie Best.

Leading to the first **adoptive T-cell therapy (CAR-T),** for kids and young adults with B-cell acute lymphoblastic leukemia.


Adrienne Skinner


Bill McCone


Carrie Best

Cancer Progress Report 2017 Congressional Briefing

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On September 13, 2017, the AACR unveiled the seventh annual AACR Cancer Progress Report on Capitol Hill. Congressman Jamie Raskin (D-MD) and Senator Sherrod Brown (D-OH) delivered opening remarks during the briefing, which included individuals whose story was told in the Report, as well as Margaret Foti, PhD, MD (hc), AACR CEO; Michael A. Caligiuri, MD, AACR president and the director of the Ohio State University Comprehensive Cancer Center; and John D. Carpten, PhD, chair of the Department of Translational Genomics at the University of Southern California Keck School of Medicine.

AACR Cancer Progress Report 2016
White House Meeting

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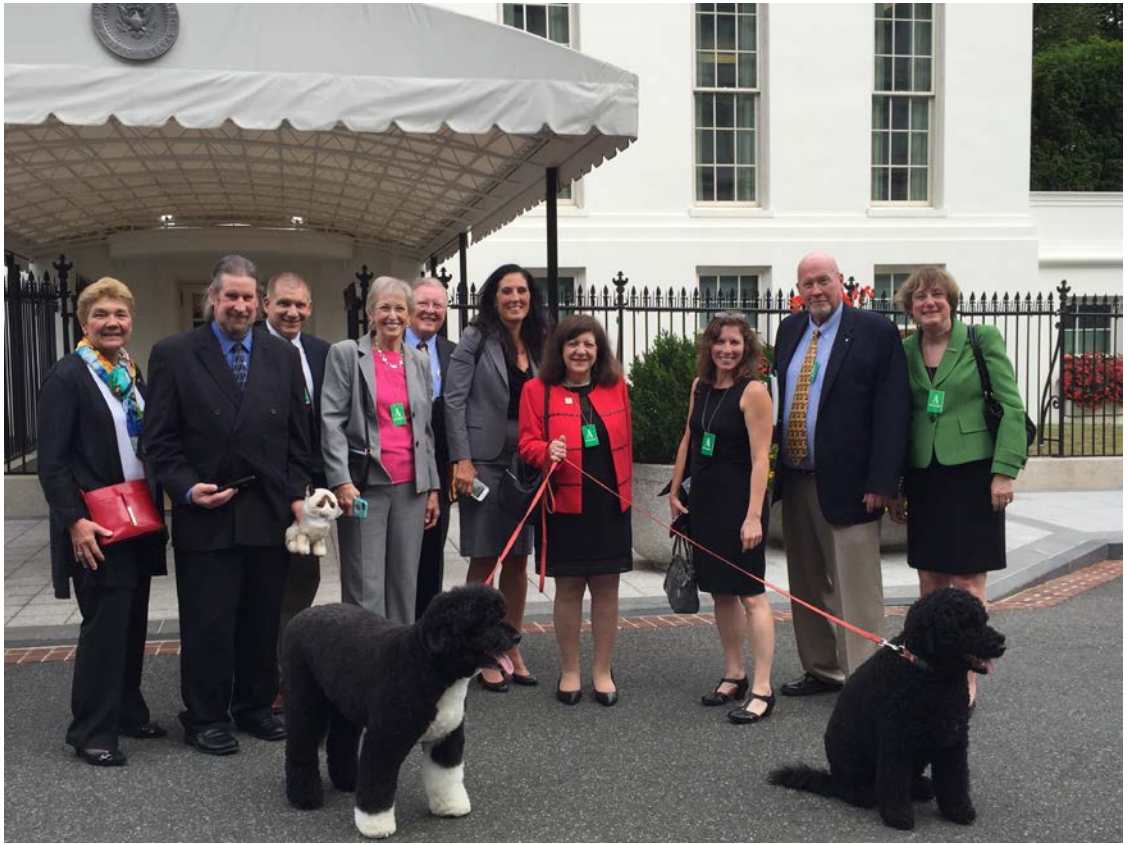

- Following the Capitol Hill briefing in 2016, the AACR leaders and survivors whose story was included in the Report met with Vice President Biden's senior staff at the White House staff to deliver the report.
- (And met President Obama's dogs!)

AACR: FOUNDING SPONSOR OF THE RALLY FOR MEDICAL RESEARCH (2013)

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2017 Rally For Medical Research Capitol Hill Day

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On September 14, over 350 advocates from 40 states participated in 242 meetings on Capitol Hill, where they urged Congress to continue robust, sustained and predictable funding increases for the NIH.

AACR SCIENTIST↔SURVIVOR PROGRAM

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- Was launched in 1999 at AACR Annual Meeting
- Unique program designed to build bridges and unity between the leaders of the scientific and cancer survivor and patient advocacy communities
- Develop collaborations among scientists and advocates to address issues in survivorship, quality of life, and science and public policy

- Increase participation in clinical trials, improve the design of clinical trials, and increase the number of effective cancer drugs
- Facilitate access to cancer information for the general public, high-risk individuals, and minority and medically underserved populations

AACR Scientist↔ Survivor Program

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AACR encourages SSP members to participate in various advocacy-related initiatives and activities, including Congressional briefings, the Rally for Medical Research Hill Day, and FDA-AACR co-sponsored workshops, as well as AACR Regulatory Science and Policy Sessions that occur at many of the annual AACR conferences and meetings.

AACR Scientist↔Survivor Program

SSP participants annually meet with FDA leaders in a special session at the AACR Annual Meeting.

The Road to Cancer Survivorship: Discover, Predict, Prevent, and Treat

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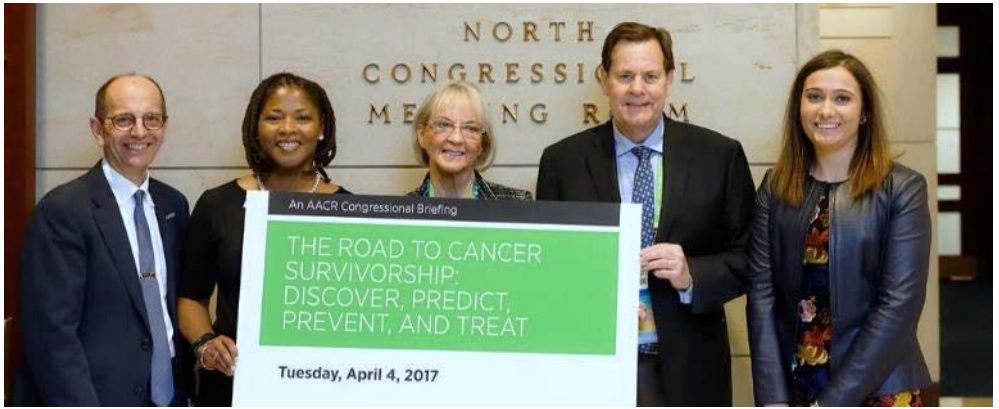
On April 4, 2017, at the AACR Annual Meeting, AACR leaders and SSP participants attended and participated in a Congressional briefing.



Regulatory Science and Policy Track at the 2017 AACR Annual Meeting

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Understanding Mechanism-based, Cardiovascular Adverse Events Associated with Immune Checkpoint Blockade: Implications for Prevention and Management

Laleh Amiri Kordestani (Co-chair) – FDA
Javid Moslehi (Co-chair) – Vanderbilt Univ.
George Demetri – Dana-Farber Cancer Institute
David Feltquate – Bristol-Myers Squibb
Shiv Pillai – Harvard Medical School
Suzanne Topalian – Johns Hopkins Kimmel Cancer Ctr.

Real World Evidence in Oncology and its Implications

Amy Abernethy (Chair) – FlatIron Health
Kassa Ayalew – FDA
Sean Khozin – FDA
Jeff Allen – Friends of Cancer Research
Jacqueline Law – Genentech, Inc.
Raymond DuBois – Medical Univ. South Carolina

Tables Turned: A Conversation with the Press about the Future of Cancer Research and Treatment

Richard Pazdur (Chair) – FDA
Adam Feuerstein – The Street
Matthew Herper – FORBES
Laurie McGinley – The Washington Post
Meg Tirrell – CNBC

Regulatory Considerations for Utilizing Liquid Biopsies in Drug and Diagnostic Development

Pasi Jänne (Co-chair) – Dana-Farber Cancer Inst.
Gideon Blumenthal (Co-chair) – FDA
Reena Philip (Co-chair) – FDA
Abraham Tzou – FDA
Suzanne Jenkins – AstraZeneca
Gary Kelloff – National Cancer Institute
Walter Koch – Roche
Howard Scher – Memorial Sloan Kettering Cancer Ctr.
Phil Stephens – Foundation Medicine
AmirAli Talasaz – Guardant Health

Immuno-oncology Combination Therapies

Geoffrey Kim (Chair) – FDA
Chao Liu – FDA
Amy Rosenberg – FDA
Daniel Chen – Genentech, Inc.
Bernard Fox – Earle A. Chiles Research Inst.
Elizabeth Jaffee –Hopkins Kimmel Cancer Ctr.
Sreeneeranj Kasichayanula – Amgen, Inc.

Advancing Clinical Trial Design in Regulatory Science and Policy*

Lisa LaVange (Co-chair) – FDA
Lillian Siu (Co-chair) – Princess Margaret Cancer Centre

Reference Materials for Next Generation Sequencing (NGS)-based Tests

Elaine Mardis (Co-chair) – Nationwide Children's Hosp.
David Litwack (Co-chair) – FDA
Zivana Tezak – FDA
Maryellen de Mars – ATCC
Girish Putcha – Freenome
Marc Salit – NIST
Kenna Mills Shaw – MD Anderson Cancer Ctr.
Jeffrey Trent – TGen

New Drugs – A Review of Recently Approved Breakthrough Therapies

Amy McKee (Chair) – FDA
Sanjeeve Balasubramaniam – FDA
Leslie Doros – FDA
Daniel Suzman – FDA
Deborah Armstrong –Hopkins Kimmel Cancer Ctr.
Dan Theodorescu – Univ. of Colorado Cancer Ctr.
Katie Thornton – Dana-Farber Cancer Institute

Recent Trends in Regulatory Science*

Julia Beaver (Co-chair) – FDA
Martha Donoghue (Co-chair) – FDA

***minisymposia**

Science Policy Track at the 2017 AACR Annual Meeting

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The Potential Impact on Cancer Patients of a Repeal or Revision of the Affordable Care Act

Gilbert S. Omenn. Univ. of Michigan, Ann Arbor, MI (Chair)

Diana Chingos. Patient Advocate, Los Angeles, CA

Chiara D`Agostino. Patient Advocate, Montclair, NJ

Ernest T. Hawk, MD, PhD, MD Anderson Cancer Center

E-cigarettes: Are they a Public Health Threat or a Useful Cessation Tool?

Benjamin A. Toll. Yale Cancer Center, New Haven, CT (Chair)

Roy S. Herbst. Yale Cancer Ctr., New Haven, CT

Rachel Grana. National Cancer Institute, Bethesda, MD

Brian A. King. Centers for Disease Control and Prevention, Atlanta, GA

Lion Shahab. University College London, London, United Kingdom

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PROGRESS REQUIRES COLLABORATIONS ACROSS AN ARRAY OF STAKEHOLDERS AND SECTORS

academic and government researchers from a diverse array of specialties;

health care providers;

regulators;

biotechnology, pharmaceutical, diagnostics, and medical device companies;

philanthropic organizations and cancer-focused foundations;

individual citizen advocates and members of advocacy groups;

federal funding organizations; and

patients, survivors, and their caregivers, family members, and friends;

policymakers;

payers.

THE VALUE OF HARNESSING PATIENTS' VOICES TO IMPROVE CANCER CARE

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- Scientists and patient advocates, working together, can fundamentally change the face of cancer!!
- Empower patients through active engagement in their own personal health care and shared decision making
- Improve access of all patient populations to the entire continuum of quality cancer care
- Improve clinical trial designs that allow for
  - Fewer patients in trials informed by genomics data
  - Better access to clinical trials, including for minorities and medically underserved or underrepresented groups
  - Patient-reported outcomes to assess the overall risk-benefit profile
- Advocate for regulatory policies that speed new drug approvals

IN SUMMARY: THE BASIS FOR CONTINUED EXTRAORDINARY PROGRESS

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- New technologies have enabled our current deeper understanding of the biology of cancer and offered opportunities in imaging, high-throughput screenings for drug discovery, precision medicine, and cancer interception
- The private sector is now developing novel compounds that alter the relevant biological proteins and processes and that are more effective than standard of care
- Colleagues in the government sector are expediting approvals while ensuring the safety and efficacy of products
- Expert health care providers are giving patients the best personalized care possible
- Patients are giving selflessly with tissues and data to advance progress

Advocates are playing a crucial role in educating patients about their options, serving on committees and thereby contributing to clinical research and regulatory policy, increasing awareness among legislators and the general public, and raising precious philanthropic funds for cancer research

ARE CANCER DRUGS GETTING BETTER?

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- Drug development decisions are being made based on the molecular basis of the disease
- "Drugs in the recent years have had exceptional response rates that we have not observed before. . . The question is not whether we (the FDA) should approve the drug, but how quickly we can approve the drug."
- This represents a new approach on the part of FDA and is the result of the new cancer science and of FDA leadership

Richard Pazdur, MD, Director, Oncology Center of Excellence, FDA.
The Cancer Letter, 2-14-14


THE CANCER LETTER
Inside information on cancer research and drug development
NCCN Policy Summit
Designing Clinical Trials in the Era of Multiple Biomarkers and Targeted Therapies
publication date: Feb 14, 2014
Previous | Next
ARE CANCER DRUGS GETTING BETTER? FDA'S RICHARD PAZDUR SAYS, "YES"
A meeting of the FDA Oncologic Drugs Advisory Committee has become a rare occurrence.
Why?
Because cancer drugs are getting better, as are applications for their approval, said Richard
of the FDA Office of Hematology and Oncology Products.
focused, and decisions are being made on the basis of
rather than the number of responses

THANK YOU FOR YOUR KIND ATTENTION!