POLICY AND ADVOCACY: AACR ACTIVITIES AND HOW YOU CAN MAKE YOUR VOICE HEARD

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Overview

- AACR Science Policy and Government Affairs
  - Who are we and what do we do?

- Washington Update

- Advocacy Activities

- How can YOU get involved?
AACR’s Office of Science Policy & Government Affairs

- Serve as an authoritative voice for important science and public policy issues
- Advocate for increased funding for cancer research and biomedical science
- Formulate policy recommendations for Congress and federal agencies (NIH, FDA, CMS, CDC, PCORI)
- Inform policymakers, scientists and the public through workshops and meetings, special briefings and conferences, and advocacy publications
- Identify regulatory science and policy areas where the AACR has the potential to stimulate positive change
- Build strong, productive alliances with research advocacy and patient advocacy groups
AACR Office of Science Policy and Government Affairs

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Vice President, Office of Science Policy and Government Affairs

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Robert A. Winn
Douglas Yee
Robert C. Young
Elizabeth M. Jaffee, ex officio
Michael A. Caligiuri, ex officio
Elaine R. Mardis, ex officio
SPGA Subcommittees

- Tobacco and Cancer
  Chaired by Roy S. Herbst, MD, PhD

- Regulatory Science and Policy
  Chaired by Kenneth C. Anderson, MD

- Health Policy
  Chaired by Gilbert S. Omenn, MD, PhD
AACR Representation on Other Policy Related Organizations and Coalitions

- National Cancer Policy Forum
- Ad Hoc Group for Medical Research (Steering Committee)
- One Voice Against Cancer (Steering Committee)
- Alliance for a Stronger FDA
- Personalized Medicine Coalition (PMC)
- Partnership to Improve Patient Care (PIPC)
- Research!America
- Friends of Cancer Research (Officer and Board Member)
- Campaign for Tobacco-Free Kids PARTNERS Coalition
- International Consortium for Action and Research on Tobacco
- Cancer Innovation Council
- Alliance for Childhood Cancer
Washington Today: A Challenging Environment, but Opportunities Exist

- Budget Battles
- Partisan Gridlock, Divisive Elections

*And yet…*
- Positive Momentum for Cancer Research
- Opportunities to Take Action
After more than a dozen years of flat funding, the House and Senate have shown strong bipartisan support for the National Institutes of Health over the past four years.

Since FY 2015, Congress has increased the NIH budget by $9 billion or 30%.

FY 2019 appropriations for NIH and other health agencies were approved on schedule for the first time in years.
- Congress still needs to pass some other appropriations bills, including the one that funds FDA.

21st Century Cures Act and Beau Biden Cancer Moonshot
- Act designates $4.8 billion for targeted initiatives at the NIH in FY 2017 – 2026.
- $1.8 billion is designated over 7 years for the Beau Biden Cancer Moonshot.
- Established the Oncology Center of Excellence at the FDA
- Other patient engagement directives; Office of Patient Affairs at the FDA
Working to Keep Medical Research a National Priority

Funding (in Billions)

$39.1 B
Current Status and Outlook

- Mid-term election outcomes will influence Congressional priorities for the next two years

- Federal Funding:
  - Continuing Resolution for remaining FY 2019 appropriations bills
  - White House has signaled expectations for cuts across the federal budget
  - Budget caps will need to be raised for FY 2020 to avoid sequestration

- Other issues: drug pricing, tax policy, criminal justice reform, immigration, addiction crisis, infrastructure…
Knowledge is power!

The eighth edition was released at a Congressional briefing in Washington, DC on September 12, 2018

### WHAT ARE CANCER HEALTH DISPARITIES?

Cancer health disparities are defined by the National Cancer Institute as adverse differences in cancer measures such as number of new cases, number of deaths, cancer-related health complications, survivorship and quality of life after cancer treatment, burden of cancer or related health conditions, screening rates, and stage at diagnosis that exist among certain segments of the population (1), including:

- **racial and ethnic minority groups**;
- **individuals who lack or have limited health insurance coverage**;
- **members of the lesbian, gay, bisexual, and transgender community**;
- **individuals with disabilities**;
- **adolescents and young adults**;
- **individuals of different ancestry**;
- **residents in certain geographic locations, including rural areas**;
- **refugees or asylum seekers**;
- **individuals of low socioeconomic status**;
- **immigrants**;
- **the elderly**.

Adapted from (1)

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*American Association for Cancer Research (AACR) Cancer Progress Report 2018*
On March 7, AACR Associate Members visited their Senators and Congressional Representatives during the 3rd Annual Early-Career Hill Day, organized by the AACR Associate Member Council (AMC) and the Office of Science Policy and Government Affairs.

The 2019 Early Career Hill Day is scheduled for the last week in February.
On April 24, representatives of the AACR and the Association of American Cancer Institutes (AACI) visited Capitol Hill to meet with Members of Congress and express gratitude for a bipartisan spending package that prioritized funding for the NIH, NCI, and FDA.

The 2019 AACR-AACI Hill Day is scheduled for April 30, 2019.
This community-wide event, organized by the AACR, brings together advocates from around the country with more than 325 organizations currently signed on as “partners.”

The 2018 Rally for Medical Research Hill Day took place on September 13.
Sharing Experiences with a Broader Audience

Cancer Survivors Share Their Stories on Capitol Hill

Posted on June 1, 2018 by AACR Press Office

The American Association for Cancer Research (AACR) is proud to support the Scientist-Survivor Program (SSP), which provides cancer survivors with opportunities to engage in cancer research, survivorship issues, advocacy, and public policy. In recent years, our survivor advocates have played an instrumental part in the AACR’s efforts to engage U.S. lawmakers in providing robust support for biomedical research.

Earlier this spring, SSP alumni Jamie Holloway of Arlington, Virginia; Richard Gelb of Beacon Falls, Connecticut; and Kim Hall Jackson of Philadelphia joined staffers from the AACR and the Association of American Cancer Institutes (AACI) in visiting members of Congress as part of AACR-AACI Hill Day. Their stories of survival bring powerful emotions to the AACR’s advocacy efforts. In honor of National Cancer Survivors Day, which will be celebrated Sunday, June 3, Jamie
The Road to Cancer Survivorship: Discover, Predict, Prevent, and Treat

Congressional Briefings bring scientists and patient advocates together to raise awareness on Capitol Hill and educate Members of Congress and their staff.
Progress in Immuno-Oncology: Delivering Hope and Clinical Benefit to Cancer Patients
AACR Tobacco and Cancer Activities

- E-cigarettes
  - Commented on FDA's Advanced Notice of Proposed Rulemaking (ANPRM) on the regulation of flavors in tobacco products
  - Supported S. 3319, a bill sponsored by Sen. Dick Durbin (D-IL) and Sen. Lisa Murkowski (R-AK), which seeks to curb the use of flavors in tobacco products including e-cigarettes
- Comments to FDA
  - Additional ANPRM comments on a tobacco product standard to lower the nicotine content of combustible cigarettes and on the regulation of premium cigars
  - Comments to the FDA nicotine steering committee regarding innovation in nicotine replacement therapies. AACR Tobacco and Cancer Subcommittee member, Dorothy K. Hatsukami, PhD, presented a summary of these comments at an FDA public hearing
- 2018 Annual Meeting Session covered the FDA's recent nicotine-focused tobacco regulatory strategy as well as the rise in e-cigarette use
“E-cigarettes: Striking a Balance Between Preventing Youth Nicotine Addiction and Helping Current Adult Smokers Quit Combustible Cigarettes”

- Held on July 18, 2018.
- Co-sponsored by Sen. Dick Durbin (D-IL) and Rep. Jackie Speier (D-CA)
- Focus: the latest science pertaining to the effects and content of e-cigarettes, and the growing problem of youth use of e-cigarettes.
HPV Elimination

- The AACR joined 70 NCI-designated cancer centers and five national cancer organizations in supporting the goal of eliminating HPV-related cancers in the United States and encouraged parents, young adults, and physicians to act to increase vaccination rates and screening access to eliminate these cancers.

- The AACR is a member of the National HPV Vaccination Roundtable.

EPA Transparency Rule

- The AACR submitted comments opposing the adoption of a 2018 proposed EPA rule, “Strengthening Transparency in Regulatory Science.”

- While the AACR supports improvements in ethical research transparency that facilitate validation and reproducibility, we are concerned that there is a lack of clarity regarding precisely how the EPA will implement the proposed Rule, and that the Agency risks excluding scientifically valid and relevant studies during its decision-making process.
Science Policy Track at Annual Meeting 2018

How the AACR is Working for You in Washington:
A Town Hall Meeting on Cancer Research
Funding and Science Policy Initiatives

The Cancer Survivorship Landscape:
Potential Focus Areas for the Future
A special session in the memory of Jimmie C. Holland, MD

A Town Hall Discussion of AACR’s
Priorities in Tobacco Policy

NCI Director’s Address and
Fireside Chat with AACR Leaders

Biden Cancer Initiative Colloquium
Looking Ahead: 2019 AACR Science and Health Policy Initiatives

- **Tobacco and Cancer**
  - 2019 AACR Annual Meeting Program to feature a discussion of international strategies to regulate e-cigarettes and will include representatives from Cancer Research U.K.
  - The subcommittee will provide comments on an upcoming FDA comment period regarding an e-cigarette product standard
  - The subcommittee will also continue its focus on issues such as tobacco use in cancer patients and graphic warning labels on cigarette packaging

- **HPV and Cancer Prevention**
  - Event on Capitol hill early 2019 promoting HPV vaccination and HPV-related cancer prevention.

- **Cancer Health Disparities**
  - Significant interest in Capitol Hill on the topic of health disparities
  - Opportunities to expand ideas from the Cancer Health Disparities Think Tank into policy initiatives
    - Congressional briefing in early 2019
    - Targeted Hill Day associated with the briefing
Partners in Progress: Cancer Patient Advocates and FDA Forum

Regulatory Science and Policy Track at AACR Annual Meeting 2018

Co-sponsored three workshops in 2018 on topics of interest to the FDA

- September 6, 2018: FDA-AACR Non-clinical Models for Safety Assessment of Immuno-oncology Products Workshop
- June 14, 2018: FDA-AACR-SGO Drug Development for Gynecological Malignancies Workshop

Partner of the “Accelerating Anticancer Agent Development Annual Workshop” along with the FDA

Submission of comments on various topics in response to FDA guidance to industry
Regulatory Science and Policy Track at Annual Meeting 2018

NGS Oncopanels: Regulatory Considerations

Cancer Genomic Reference Samples – Sequencing Consortium Results and Beyond

Biosimilars: Biological Science, Regulatory Science, and Clinical Practice

Has Pandora’s Box Been Opened? The Site-agnostic Approval of Pembrolizumab

Scientific and Regulatory Challenges in Development of CAR-T Therapy for Solid Tumors

Real World Evidence in Oncology and its Implications

Precision Therapy: When Is Better: Up Front or at Relapse?

Recently Approved Breakthrough Therapies and New Approval Endpoints

FDA Priorities: A Conversation with Deputy Commissioner Anna Abram

Implications of the 2017 FDA Reauthorization Act (FDARA) on Pediatric Cancer Drug Development
Continued Programs for 2019:
- Regulatory Science and Policy Track at AACR Annual Meeting 2019
- Co-sponsored workshops on topics of interest to the FDA
  - February 2019: FDA-AACR Real World Evidence Workshop
  - July 2019: FDA-AACR Leveraging Artificial Intelligence and Liquid Biopsy for Precision Medicine Workshop
  - FDA-NCI-AACR-ASCO Assessing Cancer Patient Tobacco Use in Oncology Clinical Trials Workshop
- AACR Science Series at the FDA

New Programs launching in 2019:
- FDA-AACR Explore Oncology Drug Development and Regulatory Science Program
- American Association for Cancer Research Policy Fellowship
- NIH-AACR Cancer, Autoimmunity, and Immunology Conference
AACR has planned events in coordination with cancer centers and members of Congress to bring attention to the local impact of cancer research and the importance of federal funding for the NIH and NCI. We will be planning more of these events in 2019 and beyond.
The AACR Needs Your Advocacy
AACR Additional Resources

- Sign up for the AACR Cancer Policy Monitor
  - Policy newsletter distributed monthly to subscribers

- AACR Legislative Action Center
  - [www.aacr.org](http://www.aacr.org)
  - Click the “Advocacy and Policy” tab

- AACR Advocates Facebook Group
Additional Opportunities

▪ Get Connected with Elected Officials
  • Sign up for your Congressman’s newsletter
  • Connect with your Congressman on Facebook
  • Follow your Congressman on Twitter

▪ Request an in-district meeting with your Member of Congress
Cancer Research Advocacy Today: A Compelling Story to Share

- We have made significant progress
- Cancer research is saving and improving millions of lives
- We are poised to achieve tremendous breakthroughs in the coming years
- There are more than 15 million cancer survivors living in the United States today
- Tell your story – Share Your Experiences, Your Hope!!
Thank you!

Questions?

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