

SITC 2019

Gaylord National Hotel
& Convention Center

Nov. 6-10

NATIONAL HARBOR, MARYLAND



Society for Immunotherapy of Cancer



Policy Update Session

Policy Committee Chair – George J. Weiner, MD

University of Iowa Holden Comprehensive Cancer Center



Society for Immunotherapy of Cancer

#SITC2019

Policy Committee Members

Chair: George J. Weiner, MD

University of Iowa Holden Comprehensive Cancer Center

Co-Chair: Jason Luke, MD

UPMC Hillman Cancer Center

Samir Khleif, MD

Georgetown Lombardi Comprehensive Cancer Center

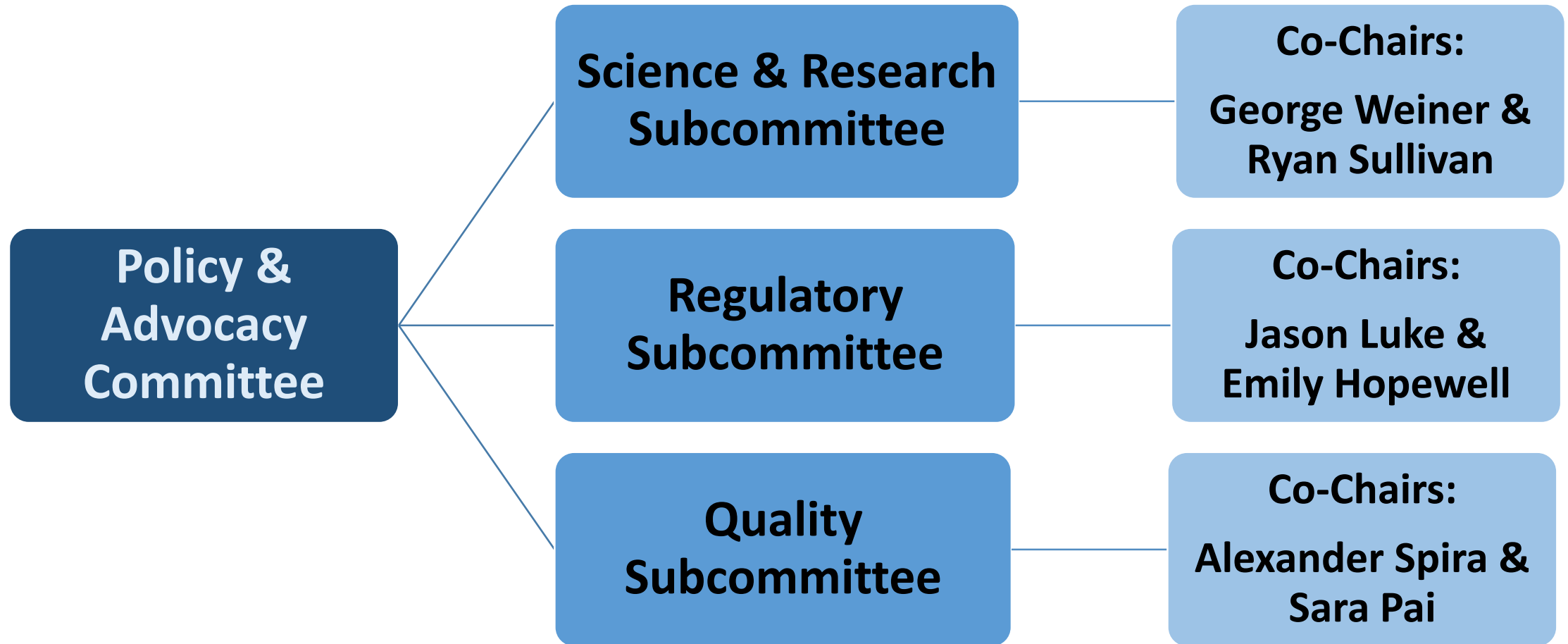
Howard L. Kaufman, MD, FACS

Replimune; Massachusetts General Hospital

Policy Committee Purpose

The Policy and Advocacy Committee reviews and analyzes immunotherapy- and oncology-related policy issues to advise the Board of Directors on the broad policy, advocacy, regulatory and value priorities of the society.

Policy & Advocacy Committee Structure



Policy Subcommittee Areas of Focus

- Quality Subcommittee
*Value framework, patient access, delivery of care, quality improvement, **CMS** coverage/reimbursement, payer relations*
- Regulatory Subcommittee
***FDA** engagement, appropriations, congressional report language to FDA OCE*
- Science & Research Subcommittee
***NIH/NCI** engagement, appropriations, congressional report language to NCI*

Capitol Hill Activities

March 28, 2019 Hill Visits

- SITC met with congressional staffers to advocate for increased NIH/NCI and FDA appropriations in FY20

June 11, 2019 Hill Visits

- SITC met with congressional staffers to discuss a proposed CMS rule affecting CAR-T reimbursement and long-term reimbursement framework for immunotherapies

October 30, 2019 Congressional Briefing

- “The Promise of Cancer Immunotherapy”



SITC Report Language Submitted for FY20

In March 2019, SITC submitted and advocated for report language concerning NCI and FDA funding. SITC-drafted FDA and NCI report language was accepted for FY2020:

- **FY20 FDA Report Language**

*Urge the FDA work with the research community and pharmaceutical industry to **develop surrogate endpoints for cancer immunotherapy** treatments that can be standardized and recognized by the entire drug development community.*

- **FY20 NCI Report Language**

*Urge the NCI to **prioritize research on combination immunotherapy treatments, resistance and duration of treatment.***

Advocating to Increase Funding

- FDA Oncology Center of Excellence (OCE)
 - The FY2020 request includes a **\$5 million increase for OCE** (from \$20 million in FY19)
- National Institutes of Health (NIH) – National Cancer Institute (NCI)
 - The Senate has proposed a **\$3 billion increase for NIH in FY20**
- Both increases are pending approval by Congress
 - Continuing Resolution ending on Nov. 21, 2019

Quality and Reimbursement Efforts

In 2019, SITC submitted three comment letters to Centers for Medicare and Medicaid Services (CMS)

- **January, 2019** – SITC opposed to the CMS Medicare Advantage Step Therapy Policy for Part B drugs (prior-authorization), which delays access to the most appropriate treatment option
- **March, 2019** – SITC opposed to the CMS proposed National Coverage Determination (NCD) for CAR-T given the lack of data and administrative burden on hospitals
- **June, 2019** – SITC supported aspects of the proposed Inpatient Prospective Payment System (IPPS) rule for FY20 and suggested CMS create a separate MS-DRG for CAR-T

I-O Quality Measure Efforts

SITC I-O Quality Expert Panel

- SITC convened key stakeholders in early 2019
 - Drafted 5 I-O quality measure concepts
 - Manuscript submitted to *Journal for ImmunoTherapy of Cancer (JITC)*

Next phase of I-O Quality Measure Development

- Further development of I-O quality measure concepts by a Quality Expert Panel

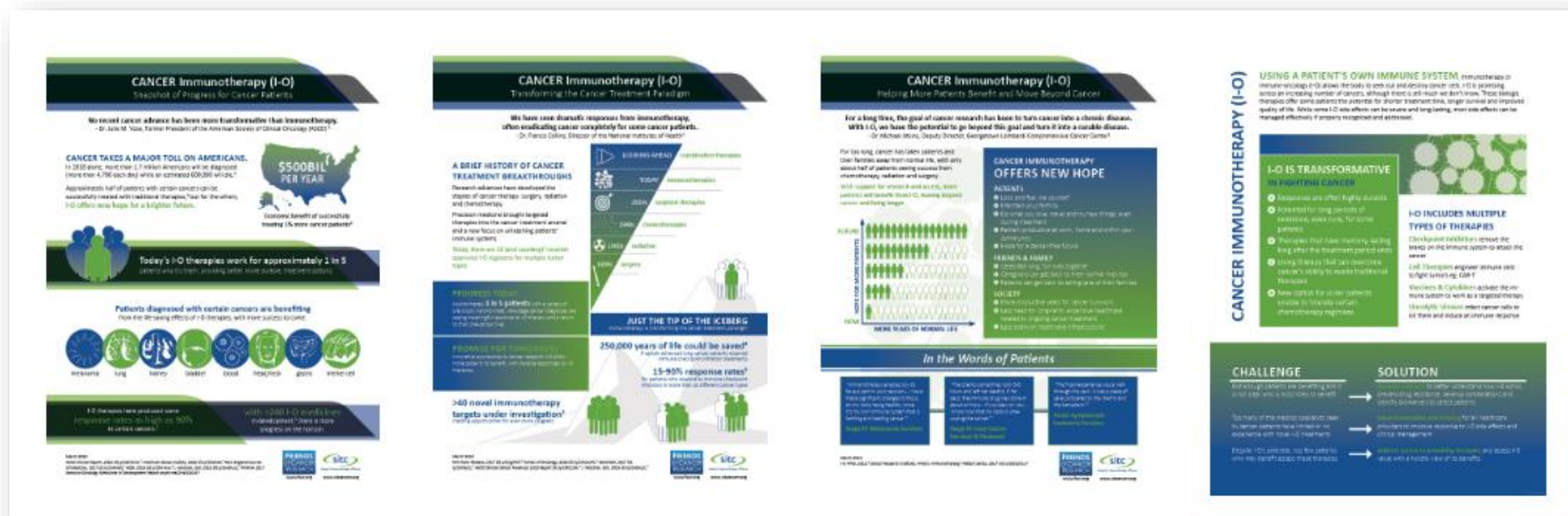
Dissemination and implementation of I-O Quality Measures

- Educate stakeholders, such as the Commission on Cancer (CoC), providers, policy makers and payers
- Consider incorporating I-O quality measures into the SITC I-O Certificate Curriculum

Patient- oriented I-O Infographics

Developed in collaboration with Friends of Cancer Research

<https://www.sitcancer.org/advocacy>



Project sponsored in part by a grant from Pfizer, Inc./EMD Serono

Defining the Value of I-O

May 17, 2019
Journal for ImmunoTherapy of Cancer (JITC)

Kaufman et al. *Journal for ImmunoTherapy of Cancer* (2019) 7:129
<https://doi.org/10.1186/s40425-019-0594-0>

Journal for ImmunoTherapy
of Cancer

POSITION ARTICLE AND GUIDELINES

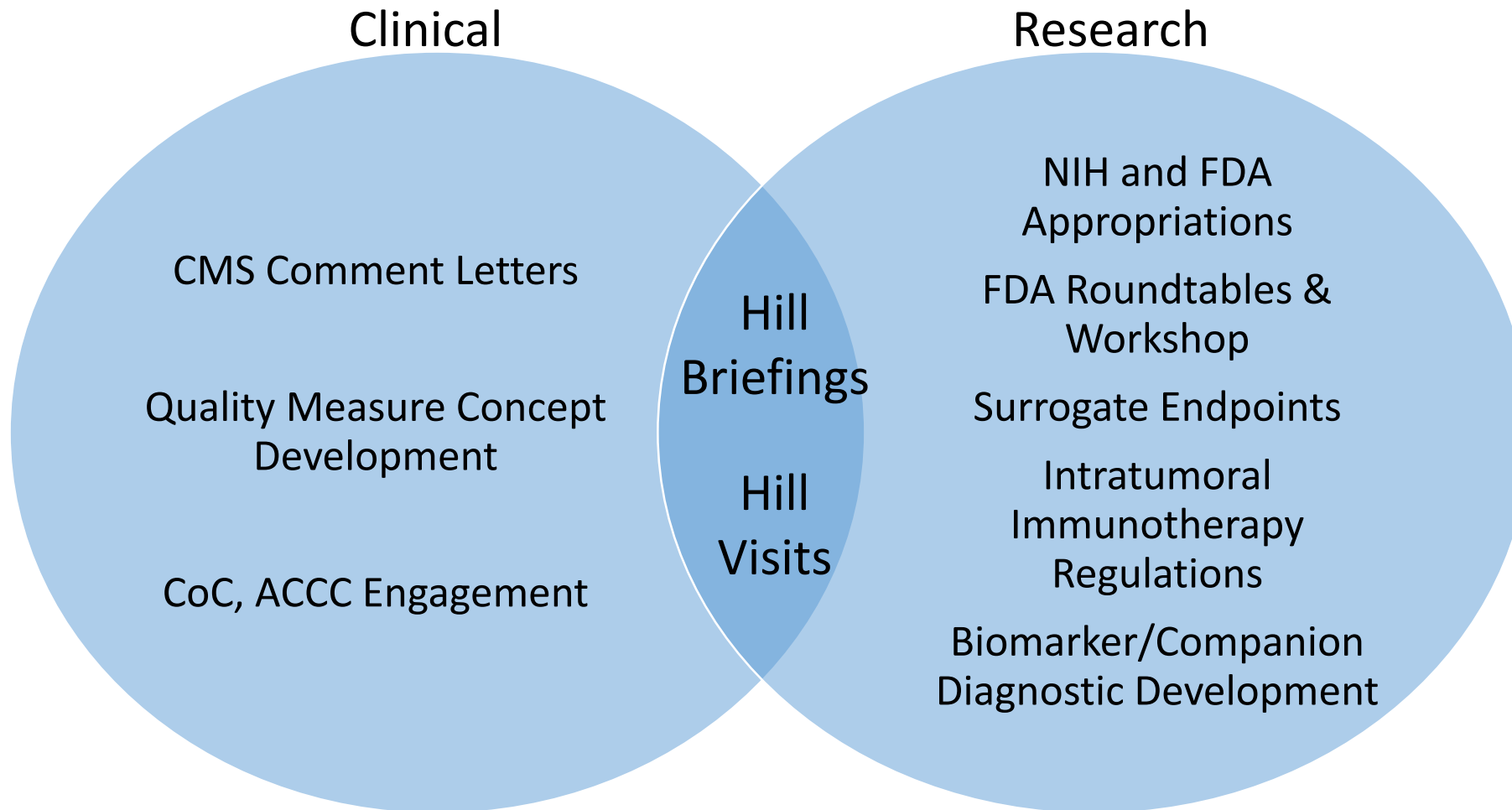
Open Access

The promise of Immuno-oncology: implications for defining the value of cancer treatment



Howard I. Kaufman¹, Michael B. Atkins², Prasun Subedi³, James Wu⁴, James Chambers⁵, T. Joseph Mattingly II⁶, Jonathan D. Campbell⁷, Jeff Allen⁸, Andrea E. Ferris⁹, Richard L. Schilsky¹⁰, Daniel Danielson¹¹, J. Leonard Lichtenfeld¹², Linda House¹³ and Wendy K. D. Selig^{14*}

2020 Policy Tactics



Call for Action

Advocacy From SITC Members

- Meet with, or write to your senators and congressmen and tell them about the promise of cancer immunotherapy and the vital role NIH funding plays in advancing the science which in turn serves their constituents