

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

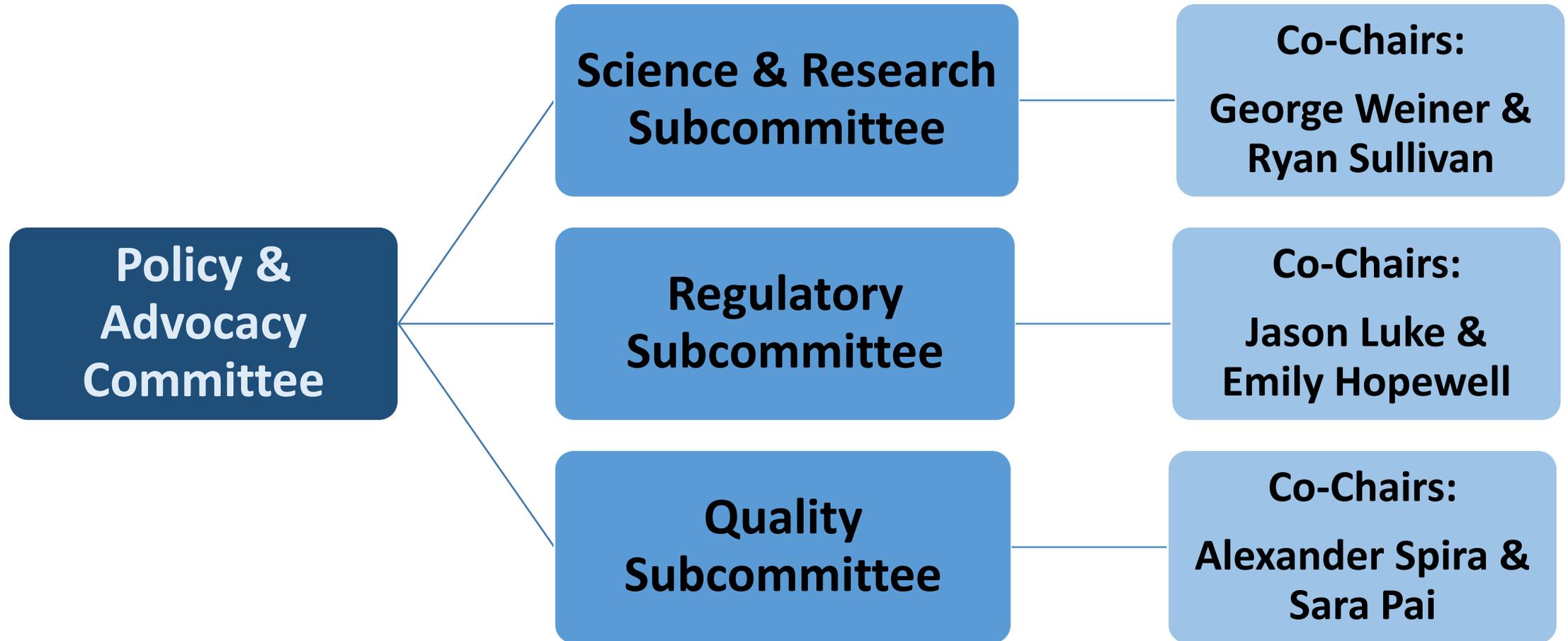
Howard L. Kaufman, MD, FACS

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

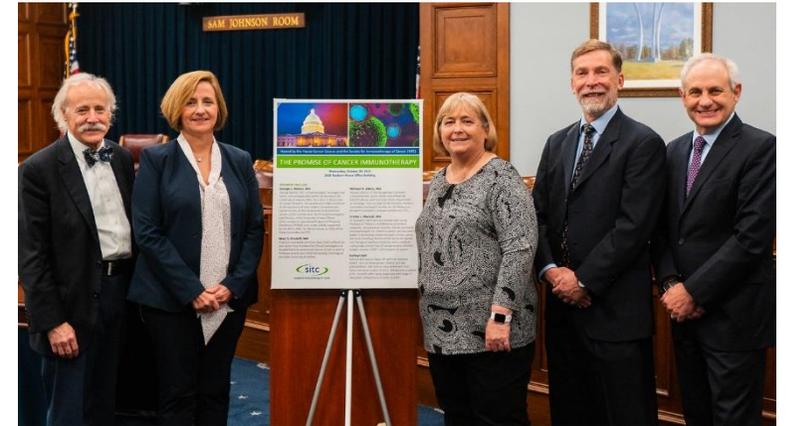
- SITC met with congressional staffers to advocate for increased NIH/NCI and FDA appropriations in FY20

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>

CANCER Immunotherapy (I-O)
Transforming the Progress for Cancer Patients

No recent cancer advance has been more transformative than immunotherapy.

CANCER TAKES A MAJOR TOLL ON AMERICANS.
In 2010 alone, more than 1.7 million Americans will be diagnosed with cancer. 4.96 million died within an estimated 100,000 weeks.
Approximately half of patients with certain cancers can't successfully respond with traditional therapies. That's where I-O offers new hope for a brighter future.

\$500BIL PER YEAR
Economic benefit of successful therapy for 1.5 million cancer patients!

Today's I-O therapies work for approximately 1 in 5 patients who have, including some novel drugs, treatment options.

Patients diagnosed with certain cancers are benefiting from the growing effects of I-O therapies, with more success found.

1-0 therapies work and used more frequently than any other cancer treatment. With 1,000 I-O therapies in clinical trials, there is hope for a brighter future.

CANCER Immunotherapy (I-O)
Transforming the Cancer Treatment Paradigm

We have seen dramatic responses from immunotherapy, often indicating cancer completely for some cancer patients.

A BRIEF HISTORY OF CANCER TREATMENT BREAKTHROUGHS
Research advances have developed the stages of cancer therapy: surgery, radiation and chemotherapy.
Precision medicine brought targeted therapies into the cancer treatment arsenal and a new focus on understanding patients' individual biology.
Today, there are 10 novel immunotherapy targets approved to treat cancer patients.

PHYSICIAN PROGRESS
Over 100 I-O patients with cancer are being treated in clinical trials. Today, there are 10 novel immunotherapy targets approved to treat cancer patients.

PROMISING NEW THERAPIES
Over 100 I-O patients with cancer are being treated in clinical trials. Today, there are 10 novel immunotherapy targets approved to treat cancer patients.

>40 novel immunotherapy targets under investigation!

JUST THE TIP OF THE ICEBERG
250,000 years of life could be saved!
15-90% response rates!
>40 novel immunotherapy targets under investigation!

CANCER Immunotherapy (I-O)
Helping More Patients Benefit and Move Beyond Cancer

For a long time, the goal of cancer research has been to turn cancer into a chronic disease. With I-O, we have the potential to go beyond this goal and turn it into a curable disease.

CANCER IMMUNOTHERAPY OFFERS NEW HOPE

ADVANTAGES

- Look for fewer side effects
- Longer survival
- Improved quality of life
- Longer survival
- Improved quality of life

LEARN & HOPES

- Learn about the latest in cancer research
- Learn about the latest in cancer research
- Learn about the latest in cancer research

LOOK UP

- Learn about the latest in cancer research
- Learn about the latest in cancer research
- Learn about the latest in cancer research

In the Words of Patients

CHALLENGE

SOLUTION

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)

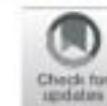
Kaufman et al. *Journal for ImmunoTherapy of Cancer* (2019) 7:129
<https://doi.org/10.1186/s40425-019-0594-0>

Journal for ImmunoTherapy
of Cancer

POSITION ARTICLE AND GUIDELINES

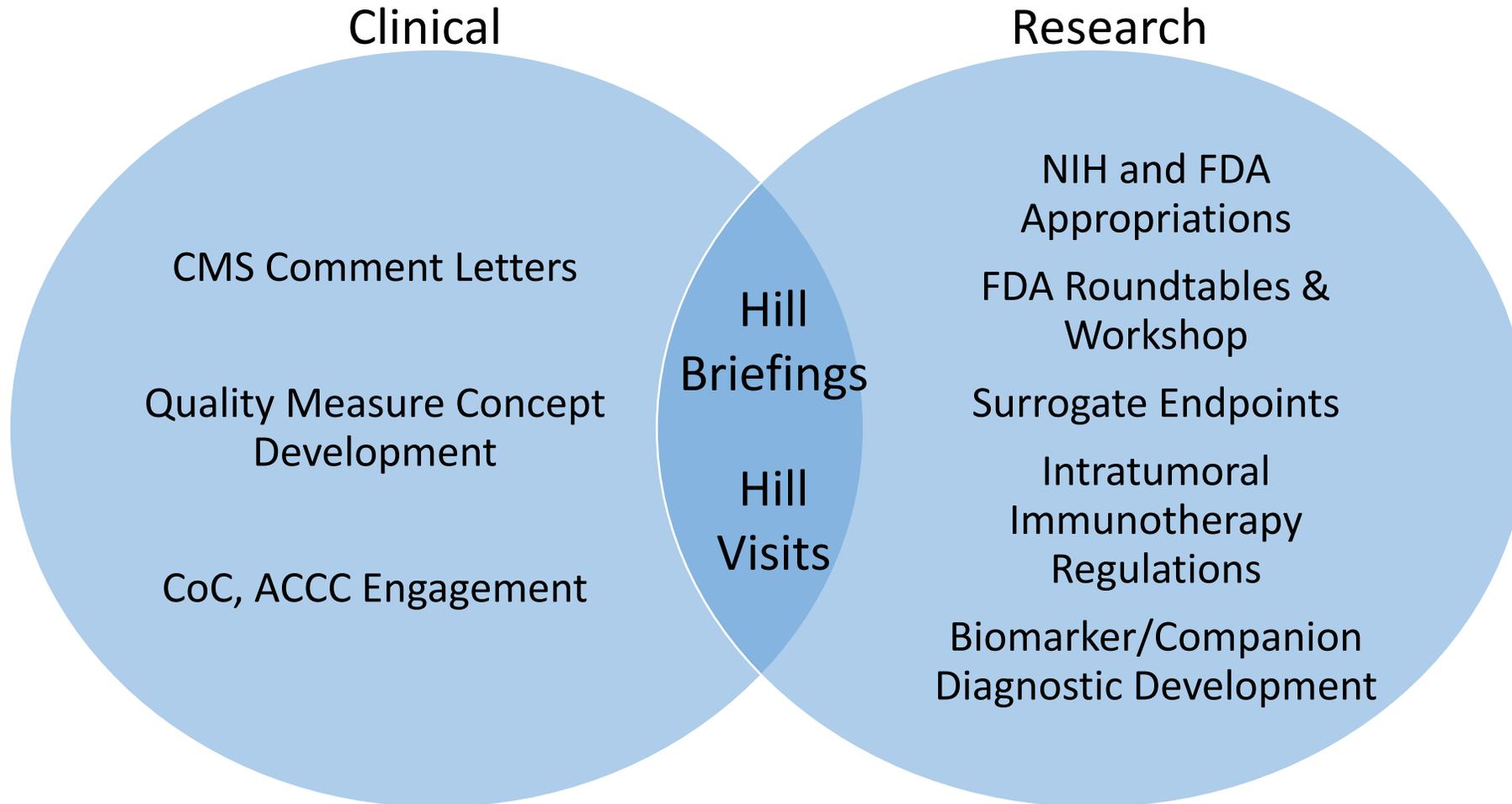
Open Access

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