Report to FNLCR

Norman E. Sharpless, MD

May 8, 2018
White House OMB coordinates with federal agencies to formulate the President’s budget proposal.

Congressional appropriations committees consider President’s proposal & prepare legislation.

Congress reconciles & finalizes appropriations legislation & sends to the President.

President signs the appropriations bill into law making funds available for NIH & NCI.

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Appropriations Outlook

FY 2019
NCI Appropriations FY 2014-2019 (in millions)

Source: NCI Office of Budget and Finance
Congressional Outreach
## RPG Pool Trends

<table>
<thead>
<tr>
<th></th>
<th>FY2013</th>
<th>FY2014</th>
<th>FY2015</th>
<th>FY2016</th>
<th>FY2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of R01</td>
<td>4003</td>
<td>3847</td>
<td>4550</td>
<td>4758</td>
<td>5263</td>
</tr>
<tr>
<td>Applications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of R01</td>
<td>582</td>
<td>578</td>
<td>623</td>
<td>650</td>
<td>650</td>
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<tr>
<td>Awards</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success rate (%)</td>
<td>15%</td>
<td>15%</td>
<td>14%</td>
<td>14%</td>
<td>12%</td>
</tr>
<tr>
<td>Non-competing</td>
<td>94%</td>
<td>97%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>support (%)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Total RPG ($B)</td>
<td>1.854</td>
<td>1.858</td>
<td>1.927</td>
<td>1.967</td>
<td>2.070</td>
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</table>
Intergovernmental Affairs
Collaborating with FDA and CMS

• Oncology Center of Excellence
• Joint Training
• Data Sharing
• Compliance advice on cell manufacture

Scott Gottlieb
Commissioner of FDA

Seema Verma
Director, CMS

• Help with NGS coverage decision
• Data Sharing
• Discussions over enhanced coverage of clinical trials
Collaborating with DoD and VA
Collaborating with DoE: RAS Modeling
Collaborating with DoE: SEER
Natural Language Processing EHR Mining

Surveillance data captured on each cancer patient

Demographics → Pathology → Molecular Characterization → Radiation → Initial Treatment → Subsequent Treatment → Survival, Progression, Patient Outcomes

Understand treatments and outcomes in the “real world”

Support development of new diagnostics and treatments through a population-based infrastructure

SEER Cancer Information Resource

Exposome

Genome
New NCAB Working Groups

Global Health
- Deborah Bruner, RN, PhD
  Emory University
- Satish Gopal, MD
  UNC Chapel Hill

SBIR / STTR
- Elizabeth Jaffee, MD
  Johns Hopkins University
- Mel Billingsley, PhD
  Pennsylvania State University

Informatics
- Mia Levy, MD
  Vanderbilt University
- Charles Sawyers, MD
  Memorial Sloan Kettering Cancer Center
Cancer Moonshot

Sept. 2016
- Blue Ribbon Panel Recommendations

- 21st Century Cures Act Authorized Funding for Cancer Moonshot

Apr.-Jun. 2017
- NCI Teams, Leaders & BSA Develop & Review Scientific Proposals Aligned with BRP Recommendations

Fall 2017
- $300M Awarded FY2018 FOAs Released
Cancer Moonshot FOAs

- Close to **50** Funding Opportunity Announcements to date and more to come
- **6** intramural initiatives
- Requirements related to data sharing and health disparities/ underserved populations
Recommendation D:

A National Cancer Data Ecosystem for Sharing and Analysis

Recommendation H:

Retrospective Analysis of Biospecimens from Patients Treated with Standard of Care
Partnership for Accelerating Cancer Therapies (PACT)

National Cancer Institute - Division of Cancer Treatment & Diagnosis

Cancer Immune Monitoring Analysis Centers (CIMACs)
- Dana-Farber
- Stanford
- Mount Sinai
- MD Anderson

Cancer Immunologic Data Commons (CIDC)
- Dana-Farber Cancer Institute

Partners:
- AbbVie
- Amgen
- Boehringer Ingelheim
- BMS
- Celgene
- Genentech
- Gilead
- GSK
- Janssen
- Novartis
- Pfizer
- Sanofi
Two New Immunotherapy Networks

<table>
<thead>
<tr>
<th>ADULT CANCERS</th>
<th>PEDIATRIC CANCERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immuno-Oncology Translational Network (IOTN, U01)</td>
<td>Pediatric Immunotherapy Discovery and Development Network (PIDDN, U54)</td>
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</table>
Developing New Cell Therapy Facility at FNLCR

Addressing the Growing Need for Clinical Grade T-cell Manufacturing
Key Focus Areas

**Workforce Development**
Support the cancer research enterprise by focusing on the workforce of cancer investigators

**Basic Science**
Reaffirm our commitment to basic science to drive novel approaches and technologies

**Big Data**
Increase data aggregation and interpretation to speed our work across the cancer enterprise

**Clinical Trials**
Fully realize the power of clinical trials through innovative design, administration, and analyses
Workforce Training & Development

- Ensure diversity and representation
- Encourage training of the right skills (Ks and Rs)
- Set aside R01 funding for early-stage investigators (ESIs)
- Method to Extend Research in Time (MERIT) – R37
Big Data

- Support the linkage of existing datasets
- Maintain a data ecosystem
- Create common data standards
- Incentivize sharing and aggregation
Today’s Agenda

• FNL: Current Operations & Future Plans
• National CRYO-EM Facility (NCEF) Update
• Overview of the NCI Experimental Therapeutics Program
• Role of Molecular Pharmacodynamics in both Drug Discovery & Development
• NCI’s Early Therapeutic Trials Network: How We Move New Agents Into The Clinic
• Accelerating Therapeutics For Opportunities In Medicine (ATOM) Update
• NCI-DOE Collaborations Working Group Report
RAS Initiative

Cryo-EM