

# NCI Director's Update

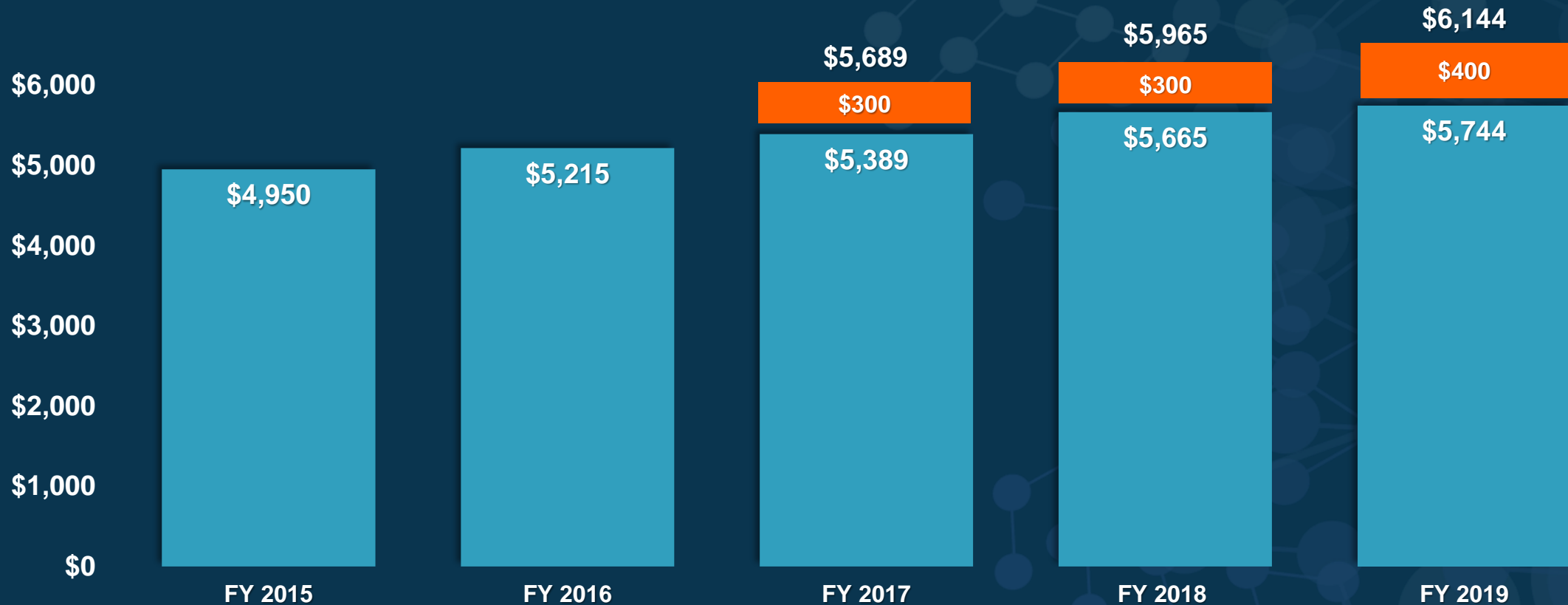
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Norman E. Sharpless, M.D.

November 7, 2018

# NCI Appropriations FY 2015 - 2019 (in millions)

*21<sup>st</sup> Century Cures  
Act funding shown  
in orange.*



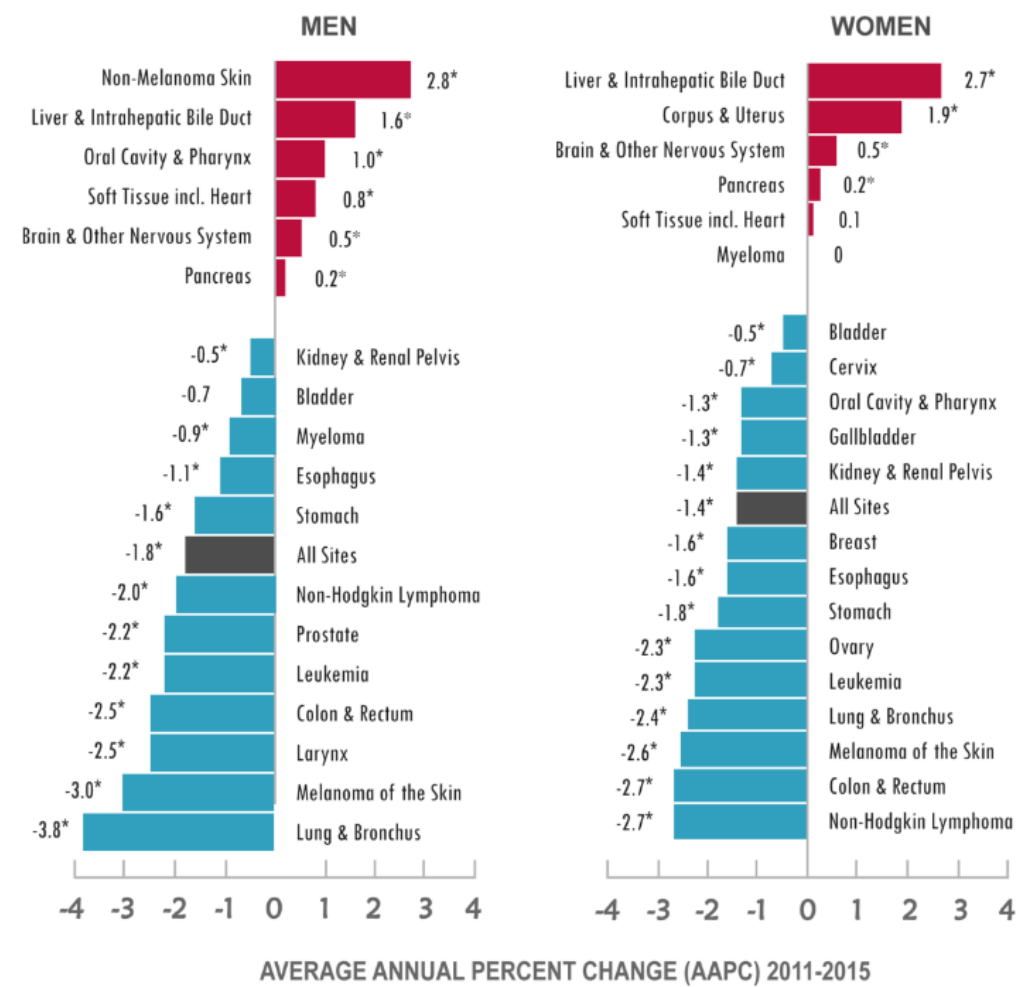
# Highlights of the Past Year

# ANNUAL REPORT TO THE NATION ON THE STATUS OF CANCER

1999 — 2015  
**CANCER  
DEATH RATES  
DECLINED**

FOR MEN, WOMEN, & CHILDREN

## NATIONAL TRENDS IN CANCER DEATH RATES





## Annual Plan & Budget Proposal

FOR FISCAL YEAR 2020

**A**s director of the National Cancer Institute (NCI), I am pleased to share our *Annual Plan and Budget Proposal for Fiscal Year 2020*.

Having been sworn in to my position a little less than a year ago, this marks my first opportunity to present, in this form, the promising results of our country's investments in biomedical research. This plan directs attention to areas where additional support has unique potential to improve cancer prevention, detection, and treatment.

To place the plan's focus squarely on those most likely to benefit from NCI research, we have included stories of patients. While each story is unique, they are not that different from that of Mike, a patient I treated for acute leukemia.

Mike started feeling poorly in 2016, and a bone marrow biopsy revealed acute myeloid leukemia (AML). I began his initial treatment with aggressive chemotherapy, which caused difficult side effects and required him to spend more than a month in the hospital. After further therapy, Mike fully recovered, and he has been in remission for more than 2 years.

Mike, and patients like him, are our true partners in



Norman E. Sharpless, M.D., with former patient Mike, whom he treated for acute leukemia in 2016.

cancer research. In addition, NCI has benefitted from concerted, sustained, and bipartisan support from



DIRECTOR'S MESSAGE: A TIME OF GREAT HOPE AND GREAT CHALLENGE



LEADING THE NATION'S PROGRESS AGAINST CANCER



UNDERSTANDING THE MECHANISMS OF CANCER



PREVENTING CANCER



DETECTING & DIAGNOSING CANCER



TREATING CANCER



ADVANCING PUBLIC HEALTH IN CANCER



STRENGTHENING THE CANCER RESEARCH ENTERPRISE



PROFESSIONAL JUDGMENT BUDGET PROPOSAL

## FY 2018 RPG POOL



Largest  
increase since  
FY 2003

## FY 2018 ESIs



NCI exceeded  
its goal of funding  
**25% more** Early-  
Stage Investigators

## FY 2019



FY 2019 enacted  
appropriation is a  
**\$179M\*** increase  
over FY 2018

*\* including Moonshot funds*

The Washington Post  
Democracy Dies in Darkness

# Researchers use immune-cell 'army' to battle another tough cancer

By Laurie McGinley June 4 [Email the author](#)

Newsweek

HEALTH

## WHAT IS IMMUNOTHERAPY?: WOMAN WITH TERMINAL BREAST CANCER SAVED BY PIONEERING TREATMENT

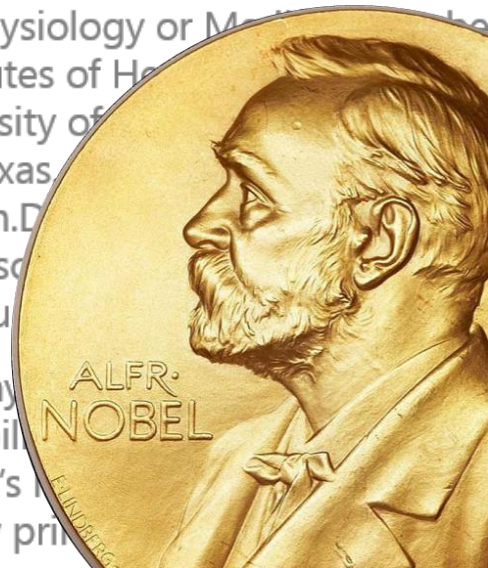
BY KASHMIRA GANDER ON 6/5/18 AT 7:03 AM

Monday, October 1, 2018

### NIH grantee wins 2018 Nobel Prize in Physiology or Medicine

The 2018 Nobel Prize in Physiology or Medicine was awarded to National Institutes of Health grantee James Allison, Ph.D., of the University of Texas MD Anderson Cancer Center, Houston, Texas, with Tasuku Honjo, M.D., Ph.D., of the Kyoto Institute, Japan, for their discovery of the inhibition of negative immune checkpoints.

The Royal Swedish Academy of Sciences announced that Allison and Honjo were awarded the prize for "stimulating the inherent ability of the immune system to attack tumor cells this year's Nobel Prize in Physiology or Medicine." The award was established in 1901 and is the highest international honor established in an entirely new prize.



# FDA Approval of Moxetumomab

## Moxetumomab Approved by FDA for Hairy Cell Leukemia

[Subscribe](#)

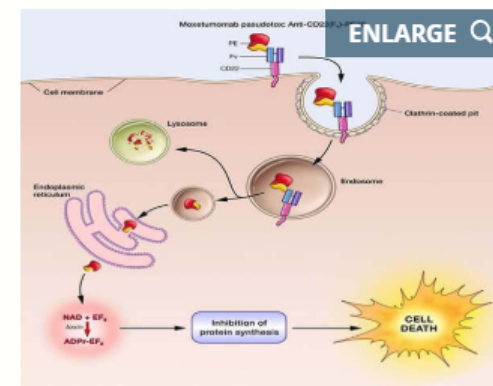
September 14, 2018, by NCI Staff

The Food and Drug Administration (FDA) has approved moxetumomab pasudotox (Lumoxiti), a bacterial toxin-based drug, for the treatment of some patients with hairy cell leukemia (HCL). The approval covers the use of moxetumomab in patients with HCL who have already undergone at least two lines of standard treatments.

The action by FDA makes moxetumomab the first treatment approved for this group of patients. The approval was based on the findings from an 80-patient clinical trial sponsored by the drug's manufacturer, MedImmune.

In the trial, approximately 30% of patients had a complete disappearance of their cancer (complete response) that lasted for a long period, and side effects from the therapy were few and mostly minor. Overall, 75% of patients in the trial had either a partial response or complete response.

Moxetumomab was originally discovered by Ira Pastan, M.D., and colleagues in NCI's [Center for Cancer Research \(CCR\)](#), and later licensed to MedImmune/AstraZeneca for clinical development.



Moxetumomab pasudotox (Moxe) binds CD22 receptors on the surface of cancerous B cells, where it is internalized and processed to release its toxic payload.

Credit: National Cancer Institute



# TAILORx

## Trial Assigning Individualized Options for Treatment (Rx)

NCI Press Release

### TAILORx trial finds most women with early breast cancer do not benefit from chemotherapy

Posted: June 3, 2018

Contact: NCI Press Office  
240-760-6600

New findings from the groundbreaking Trial Assigning Individualized Options for Treatment (Rx), or TAILORx trial, show no benefit from chemotherapy for 70 percent of women with the most common type of breast cancer. The study found that for women with hormone receptor (HR)-positive, HER2-negative, axillary lymph node-negative breast cancer, treatment with chemotherapy and hormone therapy after surgery is not more beneficial than treatment with hormone therapy alone. The new data, released at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, will help inform treatment decisions for many women with early-stage breast cancer.



Credit: iStock

The trial was supported by the National Cancer Institute

ASpirin in Reducing Events in the Elderly

# ASPREE

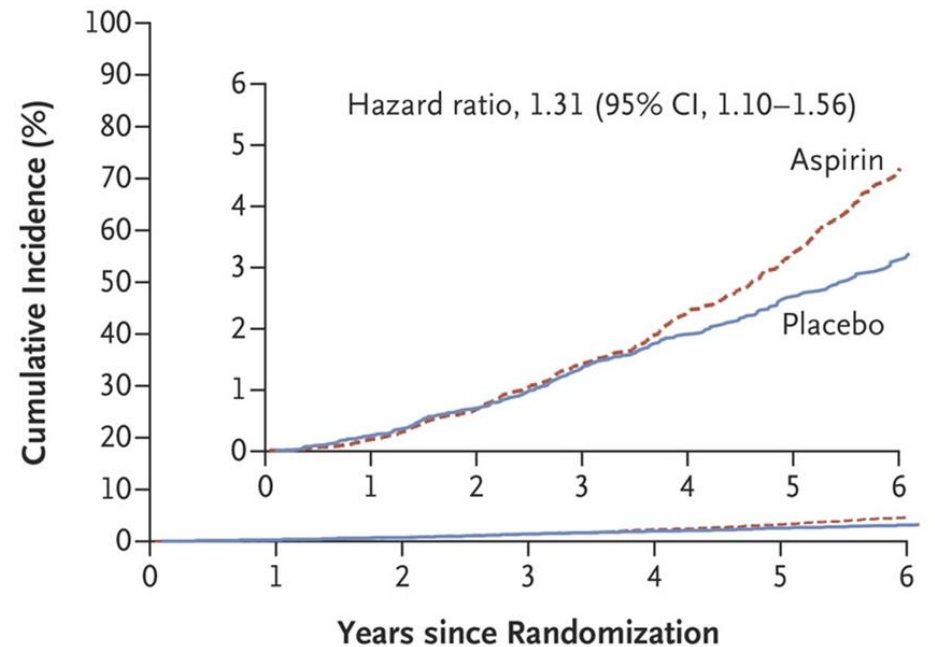
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Effect of Aspirin on All-Cause Mortality in the Healthy Elderly

J.J. McNeil, M.R. Nelson, R.L. Woods, J.E. Lockery, R. Wolfe, C.M. Reid, B. Kirpach, R.C. Shah, D.G. Ives, E. Storey, J. Ryan, A.M. Tonkin, A.B. Newman, J.D. Williamson, K.L. Margolis, M.E. Ernst, W.P. Abhayaratna, N. Stocks, S.M. Fitzgerald, S.G. Orchard, R.E. Trevaks, L.J. Beilin, G.A. Donnan, P. Gibbs, C.I. Johnston, B. Radziszewska, R. Grimm, and A.M. Murray, for the ASPREE Investigator Group\*

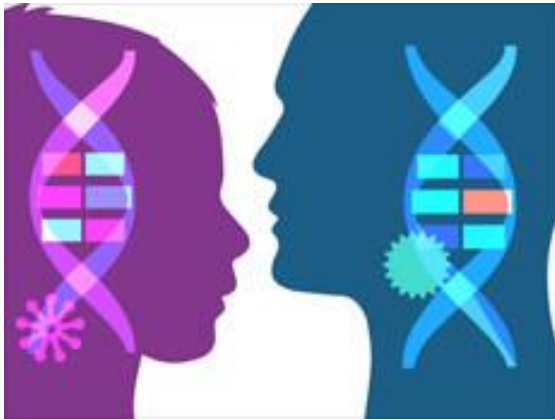
A Death Related to Cancer



No. at Risk

Aspirin	9525	9481	9408	8286	6291	4016	1495
Placebo	9589	9545	9466	8369	6367	4077	1476

# Notable NCI Research – New Projects



**Project HOPE: High-Grade Glioma-Omics in Pediatric and AYA**



**Project CARE: Glioblastoma Cellular Analysis of Resistance and Evolution**



**Hepatobiliary Cancer  
Specialized Program of  
Research Excellence  
(SPORE)**

# CMS Coverage Decision on Next-Gen Sequencing

MARCH  
16,  
2018

The Centers for Medicare & Medicaid Services (CMS) has determined that **Next Generation Sequencing (NGS) as a diagnostic laboratory test is reasonable and necessary and covered nationally**, when performed in a CLIA-certified laboratory, when ordered by a treating physician and...



# CANCER MOONSHOT

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# IMPLEMENTATION

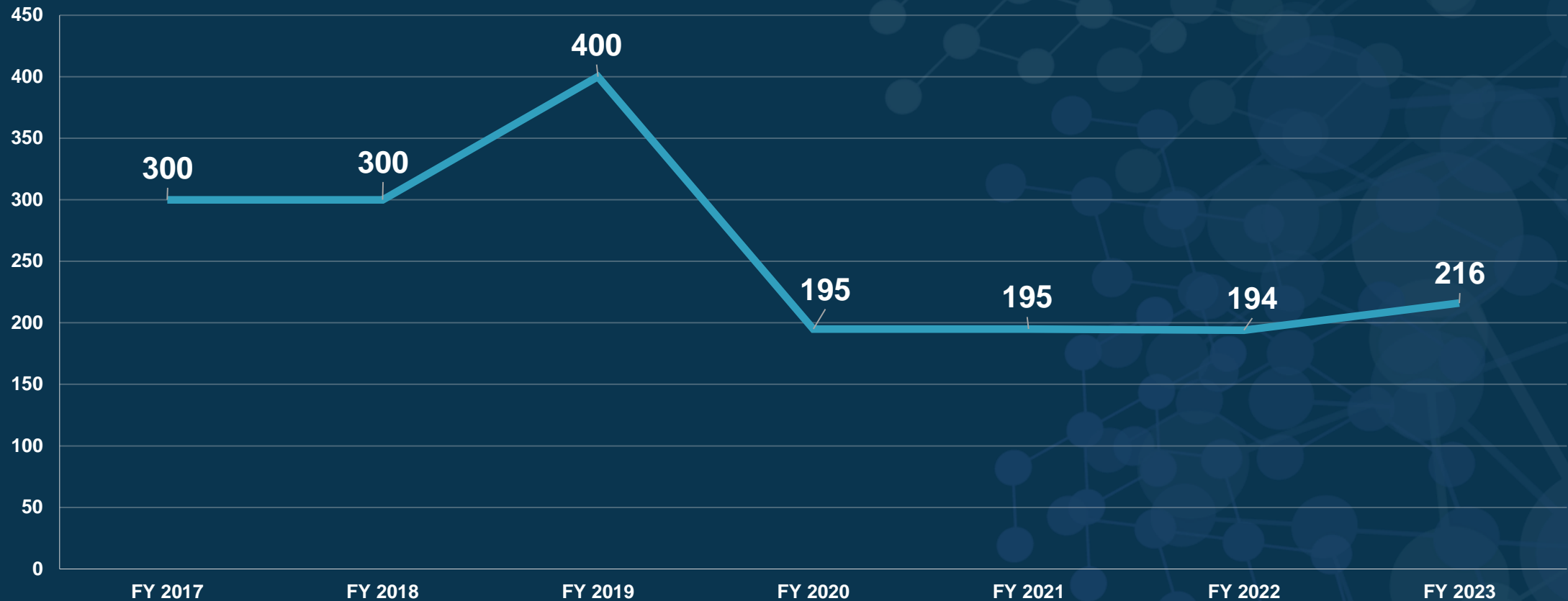
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# Cancer Moonshot Networks



- Pediatric Immunotherapy Discovery and Development
- Immuno-Oncology Translational
- Drug Resistance and Sensitivity
- Rare Tumor Patient Engagement

# Cancer Moonshot Funding Authorized Under the 21<sup>st</sup> Century Cures Act (dollars in millions)



# Opportunities & Challenges Ahead



# CTAC *Ad Hoc* Working groups

## **Glioblastoma**

Co-Chairs:

Walter J. Curran, Jr.  
M.D., F.A.C.R.

Chi V. Dang, M.D., Ph.D.

## **Radiation Oncology**

*In process*

# Leadership transitions

- Director, Center for Global Health (CGH)
- Director, Center for Bioinformatics and Information Technology (CBIIT)
- Director, Cancer Therapy Evaluation Program (CTEP)
- Director, Division of Cancer Prevention (DCP)
- Associate Director, Frederick

# 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



**NATIONAL  
CANCER  
INSTITUTE**

**[www.cancer.gov](http://www.cancer.gov)**

**[www.cancer.gov/espanol](http://www.cancer.gov/espanol)**