2019 Midwest/Northeast Section Meeting

CHICAGO

Contributing to the NIH and the National effort to cure Alzheimer's Disease

NIH
National Institute on Aging

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Our Objective

- A little about me
- Why the investment of Alzheimer's Disease (AD)
- Help me identify other steps/actions we should have considered at the NIA. History is repeating itself!
- Alzheimer's Disease and other Research at NIA; there is a difference!
- Where to find out about funding opportunities about AD; want to broaden the tent!
- HAVE FUN☺

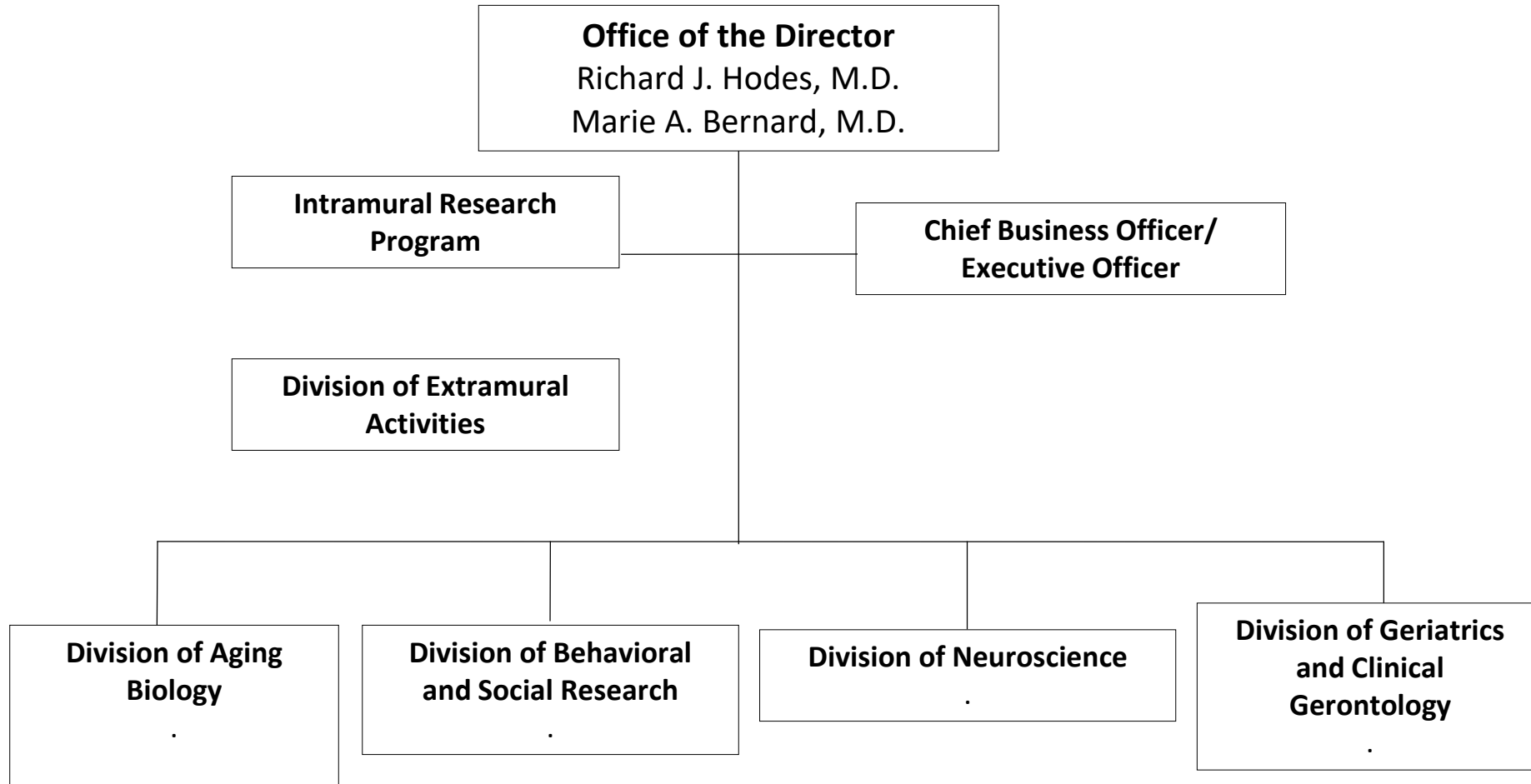# National Institutes of Health

NCI	NEI	NHLBI
NHGRI	NIA	NIAAA
NIAID	NIAMS	NIBIB
NICHD	NIDCD	NIDCR
NIDDK	NIDA	NIEHS
NIGMS	NIMH	NIMHD
NINDS	NINR	NLM
CC	CIT	CSR
FIC	NCATS	NCCIH
OD		

NATIONAL INSTITUTES OF HEALTH
National Institute on Aging
Organizational Structure

Office of the Director
Richard J. Hodes, M.D.
Marie A. Bernard, M.D.

Intramural Research Program

Chief Business Officer/ Executive Officer

Division of Extramural Activities

Division of Aging Biology
.

Division of Behavioral and Social Research
.

Division of Neuroscience
.

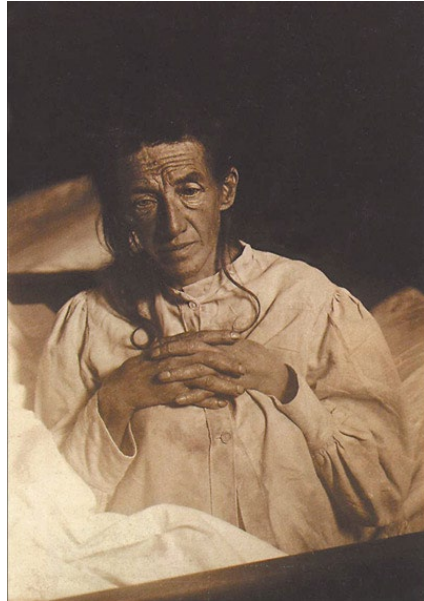**Division of Geriatrics and Clinical Gerontology**
.

One of my favorite books Copyright 1954
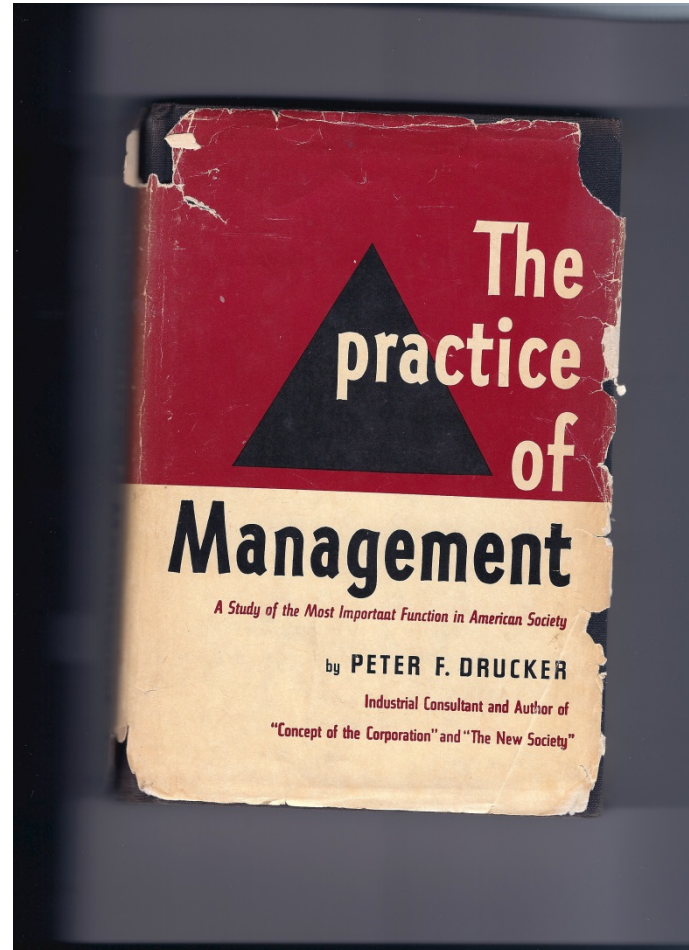
Still relevant today?

- "Today we face another major change. The new technology….."

- "The human resource, the one least efficiently used…. Holding the greatest promise for improved performance…."

- "How difficult it is to change basic attitudes – even if the need to do so is understood….."
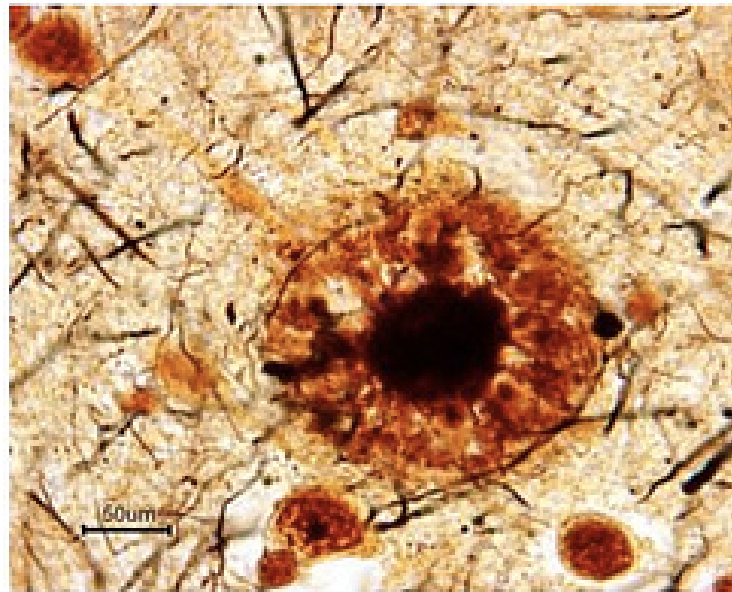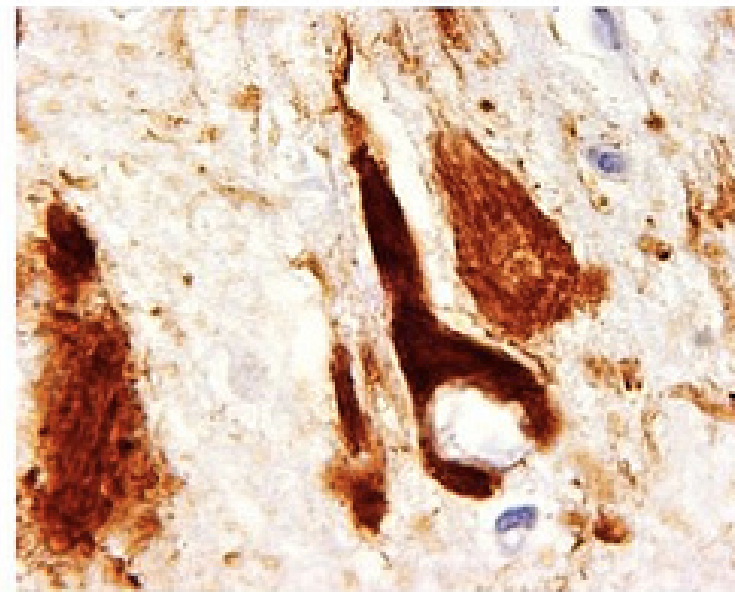
"I have lost myself."

Auguste Deter, 1850-1906
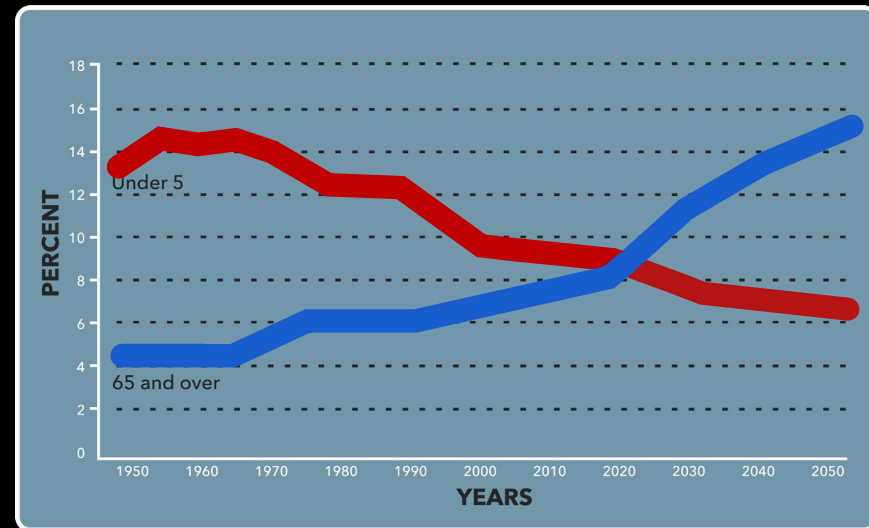
Alzheimer's Disease Pathology
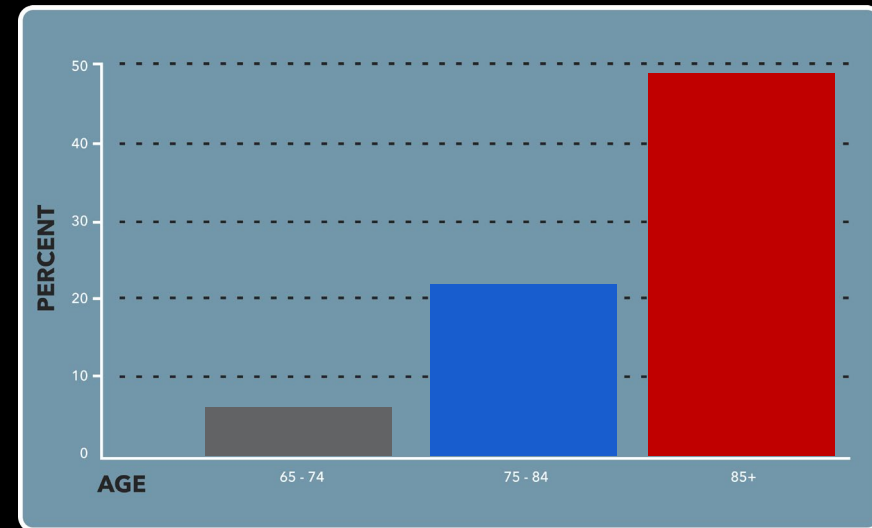
Plaques

Neurofibrillary Tangles

1906 - Plaques and Tangles Identified in Alzheimer's disease
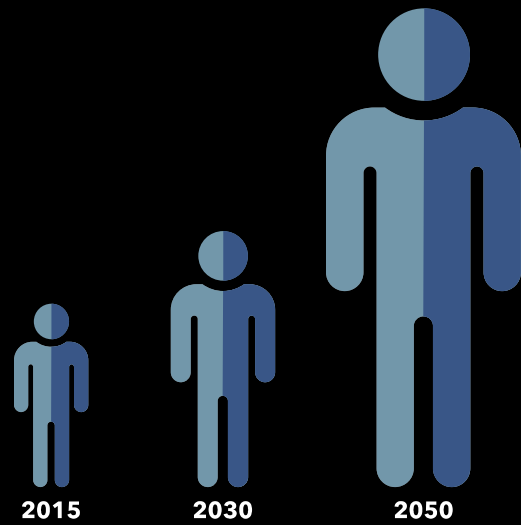
Young children and older people as a percentage of the global population: 1950 - 2050

Percent of persons with Alzheimer's disease by age

2015 **2030** **2050**

The 46.8 million worldwide cases of dementia will almost double every 20 years

US$ 818 BILLION — 2015
US$ 1 TRILLION — 2018
US$ 2 TRILLION — 2030
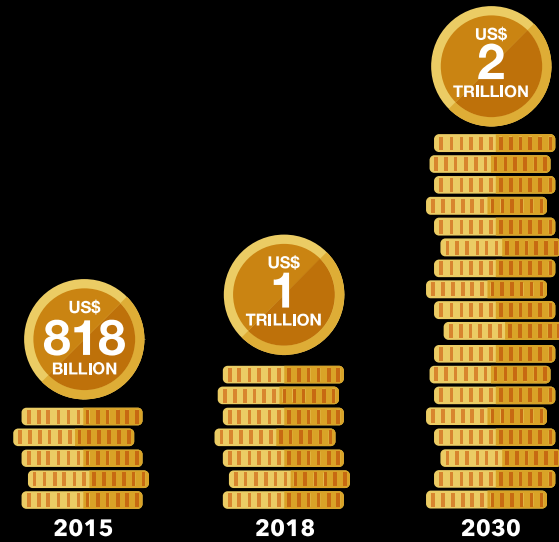
Total estimated worldwide cost of dementia in US dollars
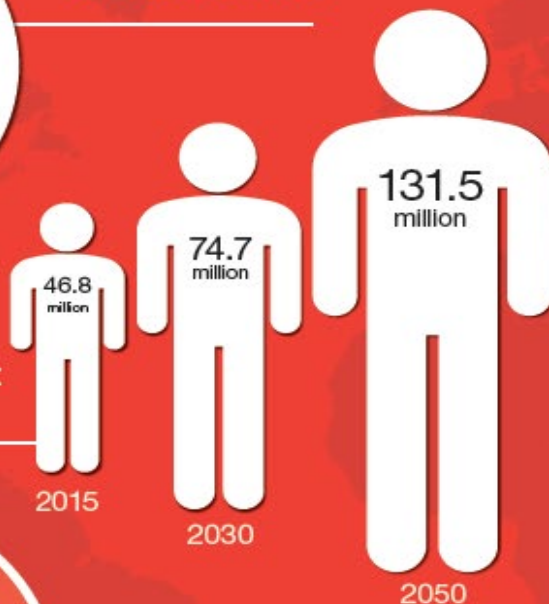
13

The global impact of dementia

Around the world, there will be 9.9 million new cases of dementia in 2015,

one every 3 seconds

46.8 million people worldwide are living with dementia in 2015.

This number will almost double every 20 years.

46.8 million — 2015

74.7 million — 2030

131.5 million — 2050

68% 2050

Much of the increase will take place in low and middle income countries (LMICs): in 2015, 58% of all people with dementia live in LMICs, rising to 63% in 2030 and 68% in 2050.
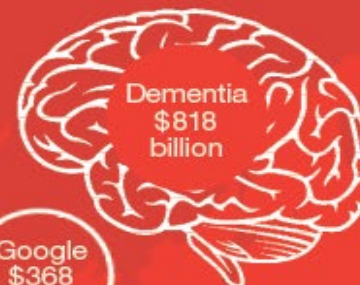
US$ 818 BILLION — 2015

US$ 1 TRILLION — 2018

The total estimated worldwide cost of dementia in 2015 is US$ 818 billion. By 2018, dementia will become a trillion dollar disease, rising to

US$ 2 trillion by 2030

If global dementia care were a country, it would be the

18th largest economy

in the world exceeding the market values of companies such as Apple and Google

Apple $742 billion

Google $368 billion

Dementia $818 billion

(source: Forbes 2015 ranking).

EUROPE 10.5 MILLION

THE AMERICAS 9.4 MILLION

AFRICA 4.0 MILLION

ASIA 22.9 MILLION

This map shows the estimated number of people living with dementia in each world region in 2015.

We must now involve more countries and regions in the global action on dementia.

Alzheimer's Disease International
The global voice on dementia

The World Alzheimer Report 2015 was independently researched by King's College London and supported by Bupa.

The National Alzheimer's Project Act

- Signed into law in January 2011
- The law calls for
  - An annually updated national plan
  - Annual recommendations for priority actions to
    - improve health outcomes for individuals with AD
    - lower costs to families and government programs
  - The annual evaluation of all federally funded efforts in Alzheimer's research/care/services – and outcomes
  - The creation of an Advisory Council on Alzheimer's Research, Care, and Services

https://aspe.hhs.gov/national-alzheimers-project-act

National Plan to Address Alzheimer's Disease and Related Dementias

Goal 1: Prevent and Effectively Treat
   Alzheimer's Disease and Related
   Dementias by 2025

Goal 2: Enhance Care Quality and Efficiency

Goal 3: Expand Supports for People with
   Alzheimer's Disease and Related Dementias
   and Their Families

Goal 4: Enhance Public Awareness and Engagement

Goal 5: Improve Data to Track Progress

Summer of 2015, 2016, 2017, 2018

- The FY 2016 Budget Process is moving along!
- House and Senate both have large increases in Report Language for Alzheimer's Disease (AD).
- Will the increase materialize or not?
- And if it does, is it a one shot increase, or an increase to the base?

TSUNAMI

NIA Planning Summer 2015

- The Research Community will they be ready?
- How much risk is acceptable?
- Engagement of other NIH Institutes
- NIA internal processes
  - Staffing (Grants, Review, Budget/Finance, Program, Support, others?)
  - Scenario planning – who knows!
  - Intramural?
  - Space (We were in the middle of substantial space reductions)
  - Demands on Leadership

Implementation of Additional AD Funding

- Twenty-two AD/ADRD FOAs were released by the NIA between 2014-2016 for potential funding

  - They cover a range of research areas spanning

Basic Research	Translational Research	Clinical Research

AD/ADRD Targeted Increases

2011	2012	2013	2014	2015	2016	2017	2018	2019
National Alzheimer's Project Act (NAPA)	**$50 M*** redirected within NIH budget	**$40 M*** redirected within NIH budget	**$100 M** additional approp	**$25 M** additional approp	**$350 M** additional approp	**$400 M** additional approp	**$414 M** additional approp	

$425 M in additional appropriations as of 09/28/18

*one-year money

Years displayed are Fiscal Years

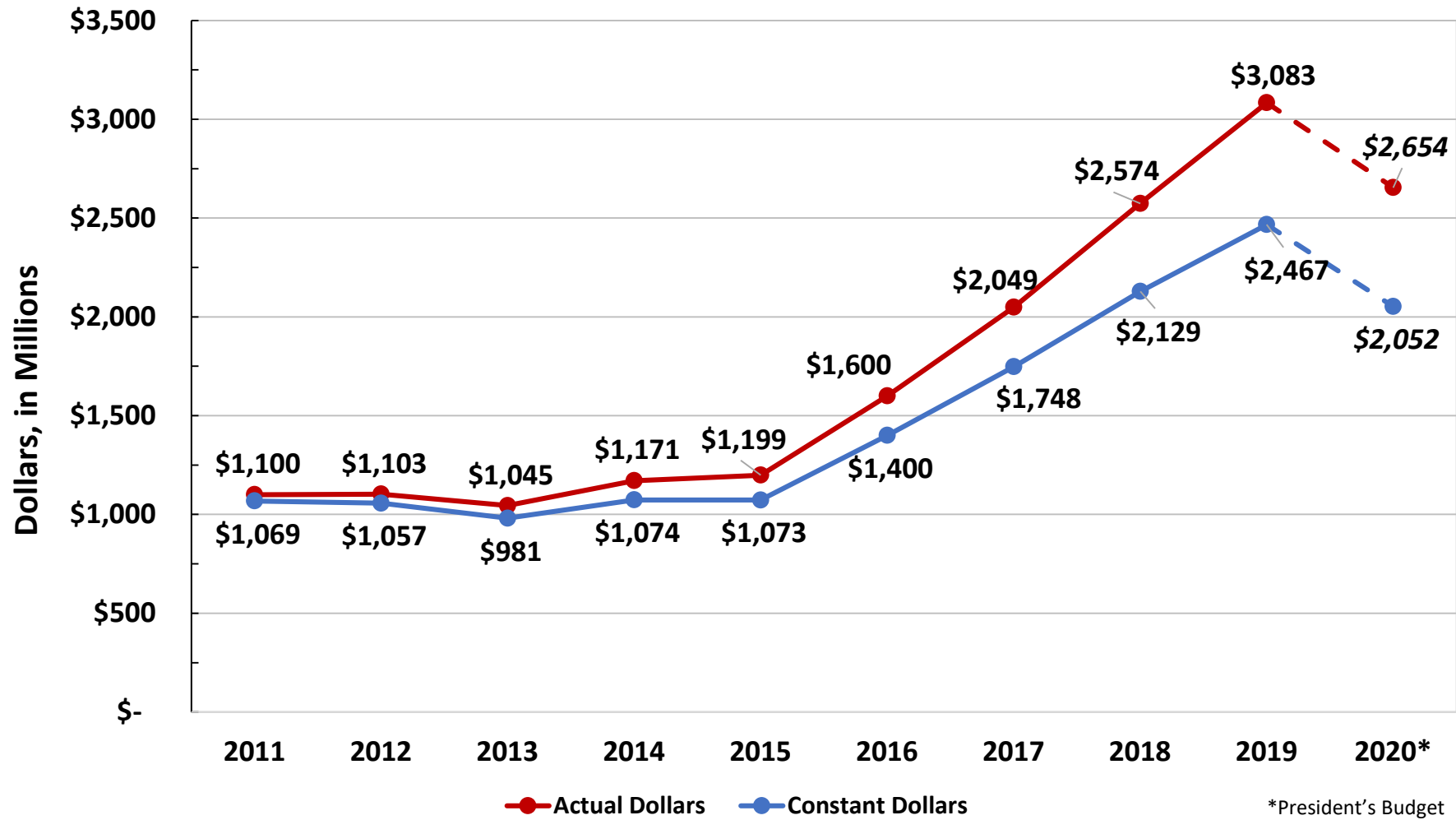# NIA Appropriations and President's Budget
Fiscal Years 2011-2020

Dollars, in Millions

- 2011: $1,100
- 2012: $1,103
- 2013: $1,045
- 2014: $1,171
- 2015: $1,199
- 2016: $1,600
- 2017: $2,049
- 2018: $2,574
- 2019: $3,083
- 2020*: $2,654
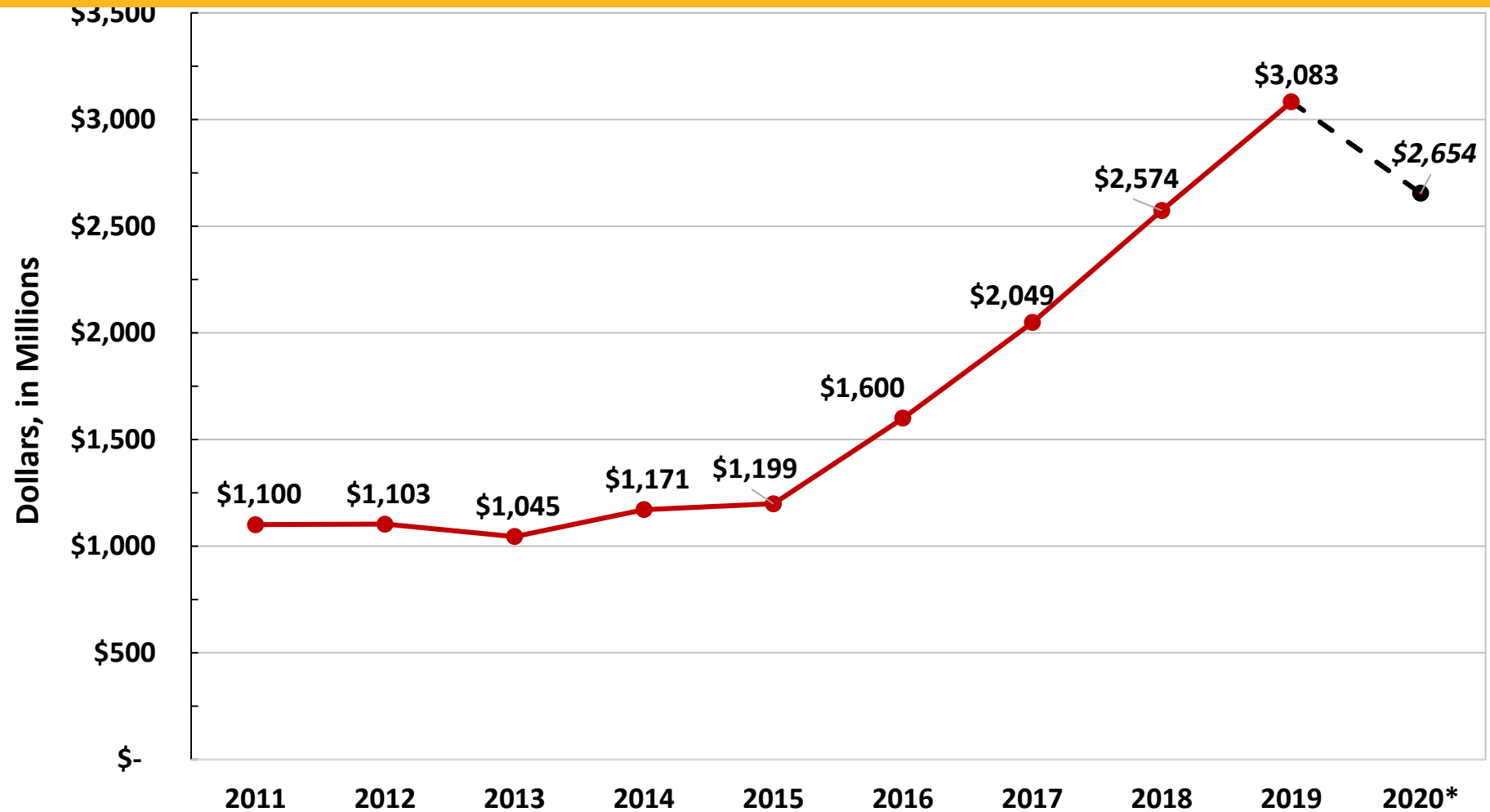
*President's Budget

NIA Appropriations and President's Budget Fiscal Years 2011-2020

Dollars, in Millions

Actual Dollars:
- 2011: $1,100
- 2012: $1,103
- 2013: $1,045
- 2014: $1,171
- 2015: $1,199
- 2016: $1,600
- 2017: $2,049
- 2018: $2,574
- 2019: $3,083
- 2020*: $2,654

Constant Dollars:
- 2011: $1,069
- 2012: $1,057
- 2013: $981
- 2014: $1,074
- 2015: $1,073
- 2016: $1,400
- 2017: $1,748
- 2018: $2,129
- 2019: $2,467
- 2020*: $2,052

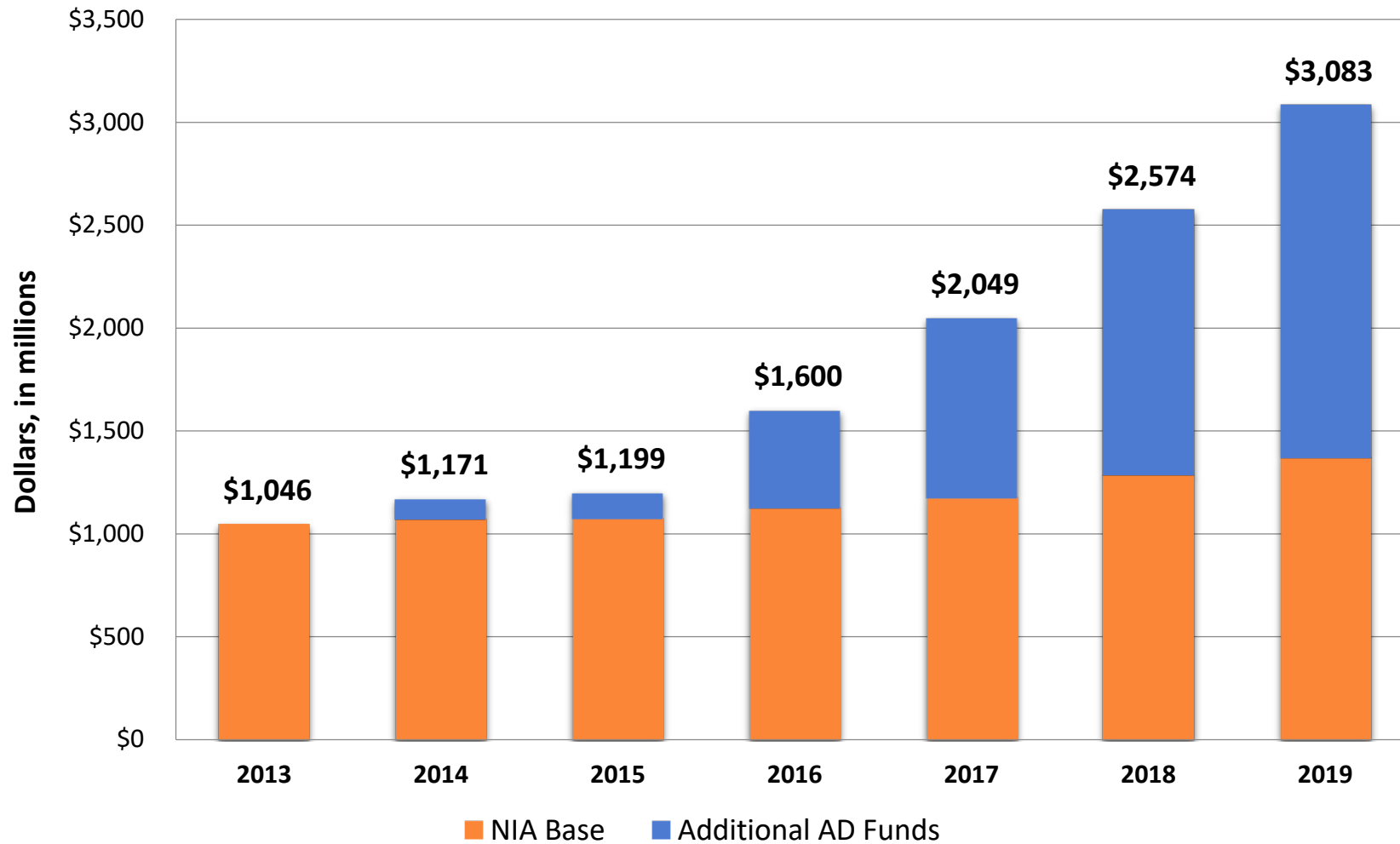—●— Actual Dollars —●— Constant Dollars

*President's Budget

Appropriations Budget Growth since FY2011-2019
Actual Dollars: +$1,983.0 M (+180.2%)   **Constant Dollars: +$1,398.2M** (+130.9%)

NIA Appropriations
FY 2013-2019

Dollars, in millions

Year	Total
2013	$1,046
2014	$1,171
2015	$1,199
2016	$1,600
2017	$2,049
2018	$2,574
2019	$3,083

■ NIA Base ■ Additional AD Funds

FY 2019 Budget Status

H.R. 6157

- On September 28, 2018, the President signed the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, giving the NIH a full Fiscal Year budget.
- **The Act provides**
  - **$39B for NIH (~$2B increase)**
  - $500M for research related to Opioids
  - $100 for Cancer Moonshot
  - $40M for universal flu vaccine
  - **$425M additional funds for AD research**
  - **$3.1B for NIA (including the $425M for AD)**
  - $86M for All of Us
  - $29M for the BRAIN initiative

FY 2019 Budget Status –
Funding Increases Across the Board

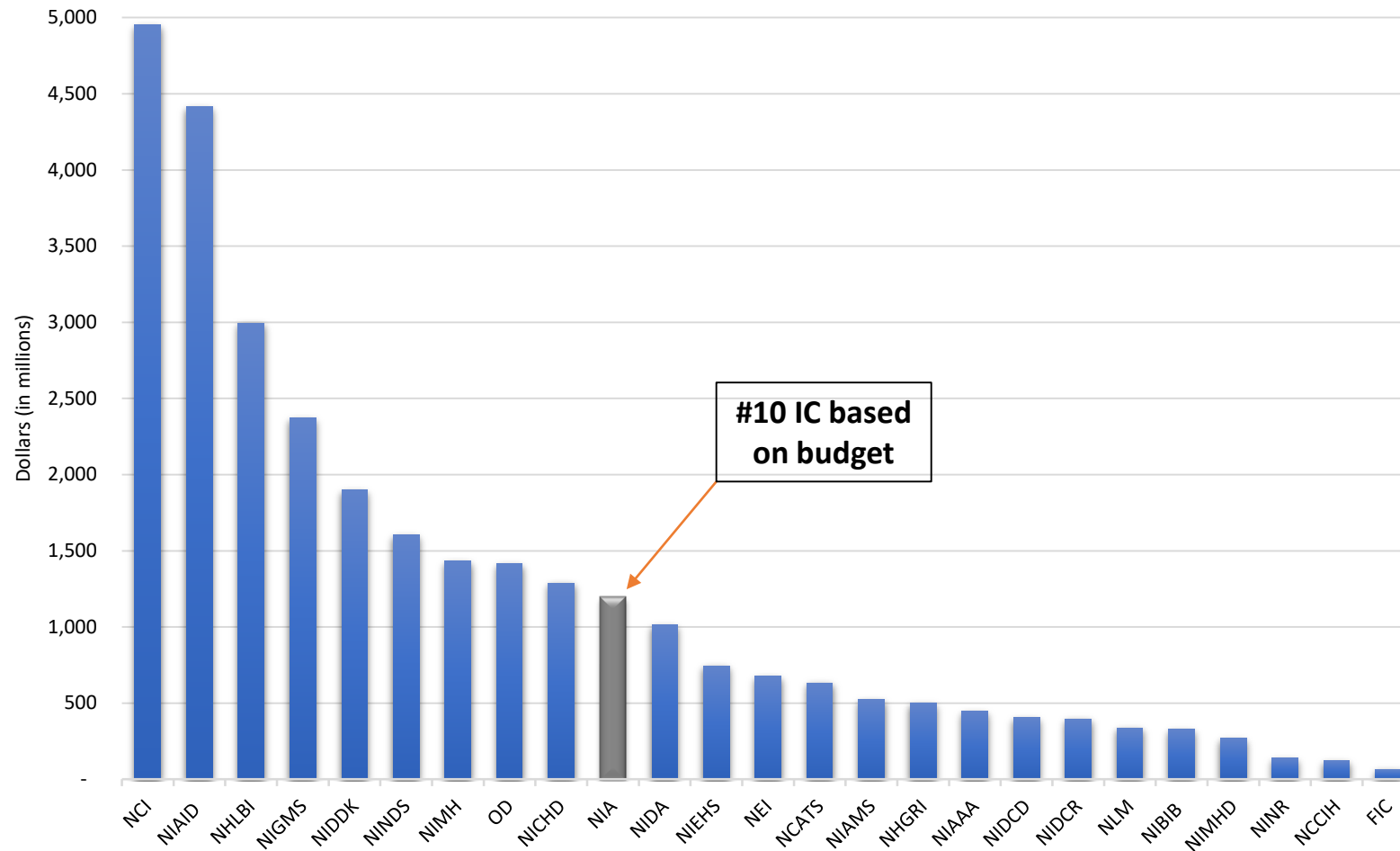**$39 Billion for the NIH**

→ **$40M for universal flu vaccine**

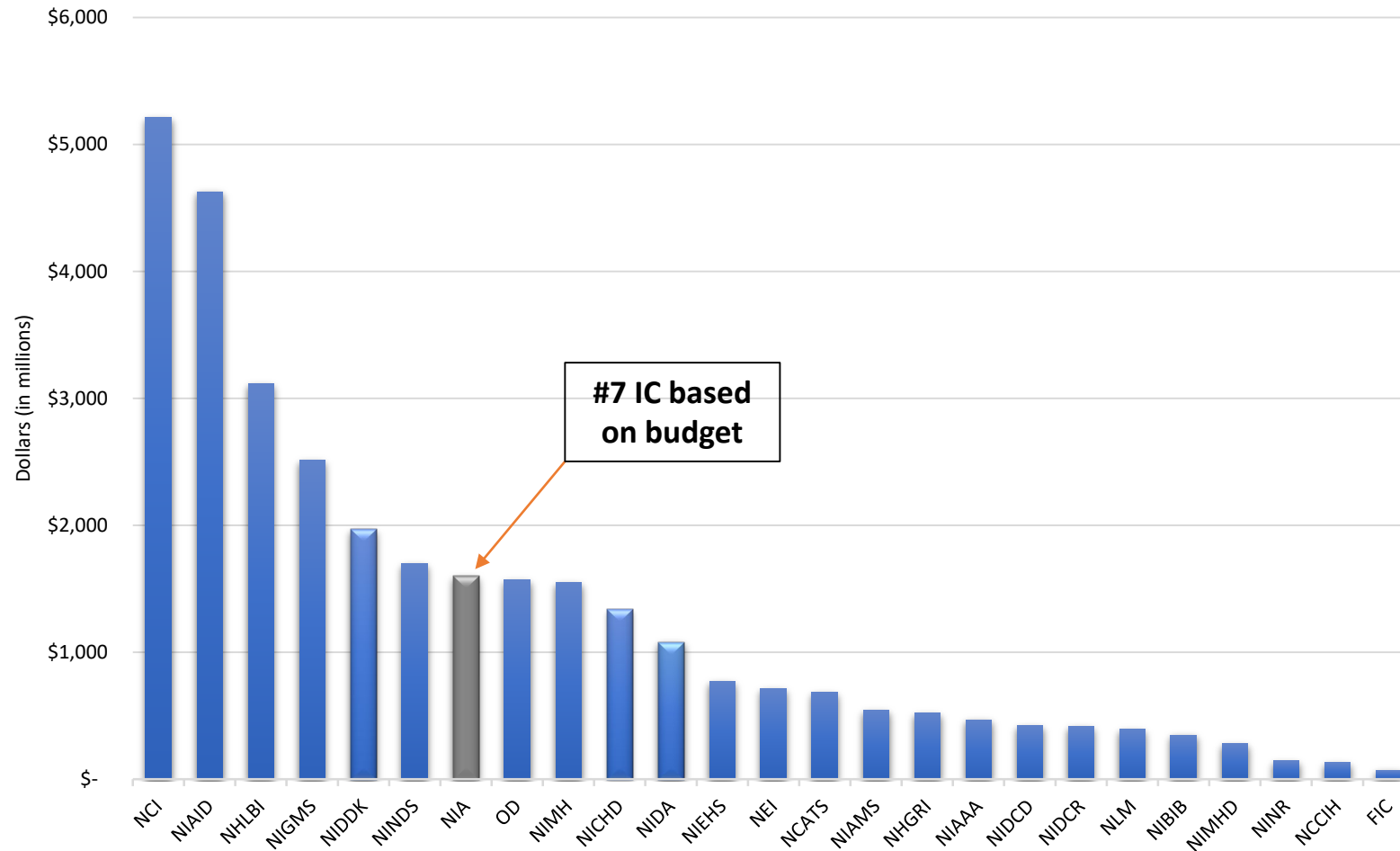→ **$29M increase for BRAIN**

→ **$86M increase for All of US**

→ **$425M increase for AD/ADRD**

- **$3.1B for the NIA**
- $84M increase for NIA research; percent increase comparable to other ICs
- **All divisions will benefit**
  - ➢ DBSR
  - ➢ DGCG
  - ➢ DAB
  - ➢ DN

FY 2015 NIH Operating Plan Budgets

FY 2016 NIH Operating Plan Budgets

#7 IC based on budget

Dollars (in millions)

Categories: NCI, NIAID, NHLBI, NIGMS, NIDDK, NINDS, NIA, OD, NIMH, NICHD, NIDA, NIEHS, NEI, NCATS, NIAMS, NHGRI, NIAAA, NIDCD, NIDCR, NLM, NIBIB, NIMHD, NINR, NCCIH, FIC
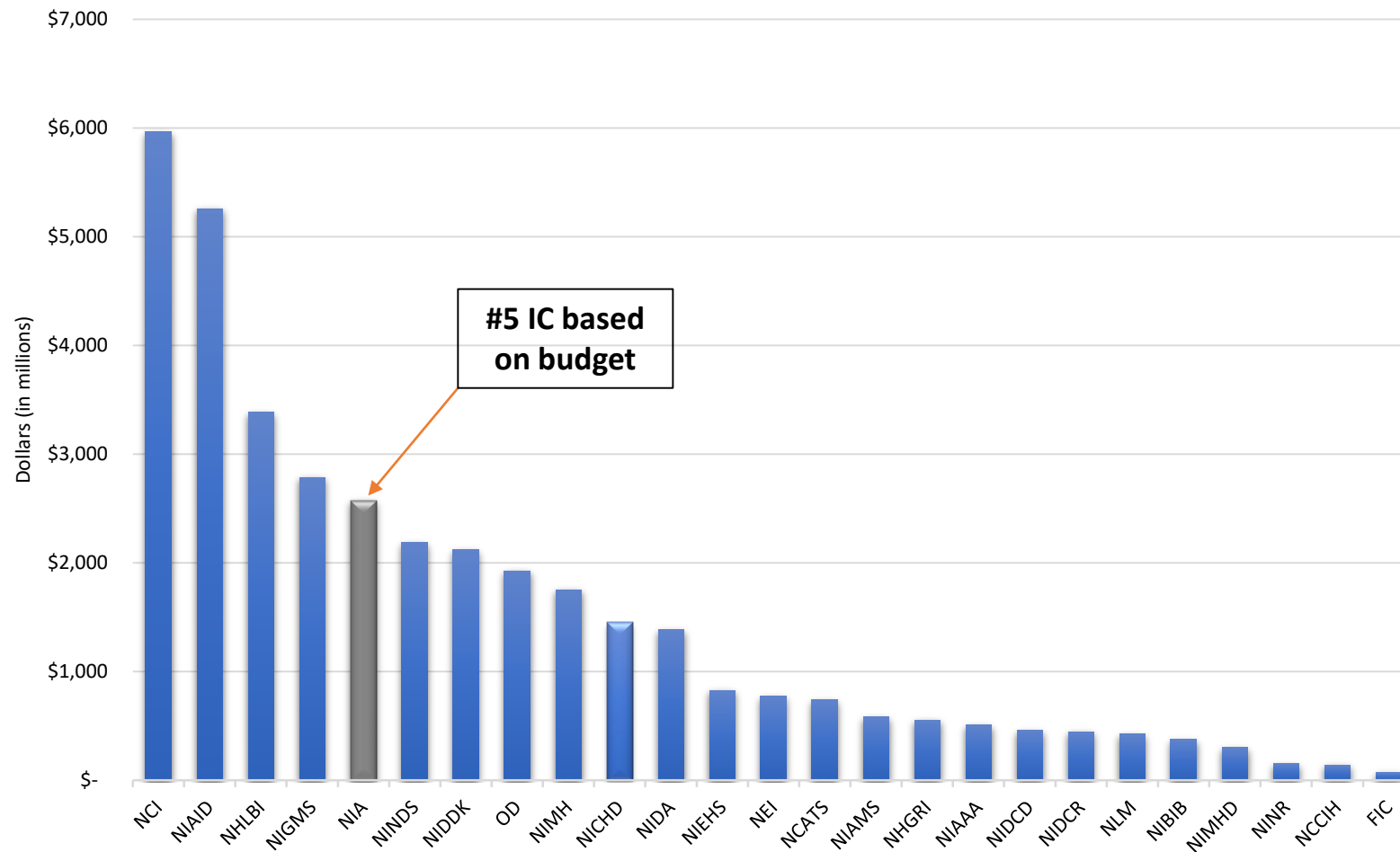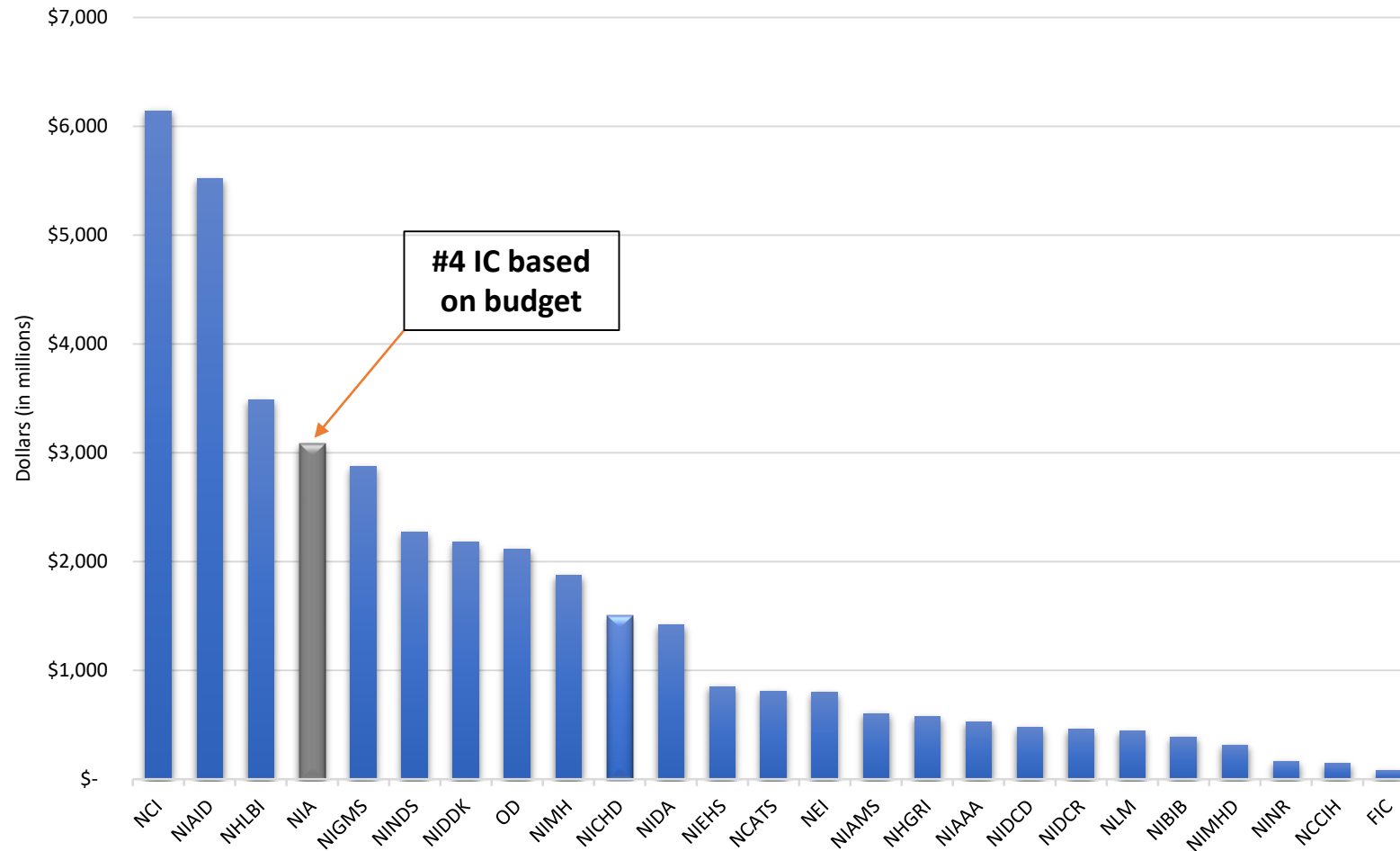
FY 2017 NIH Operating Plan Budgets
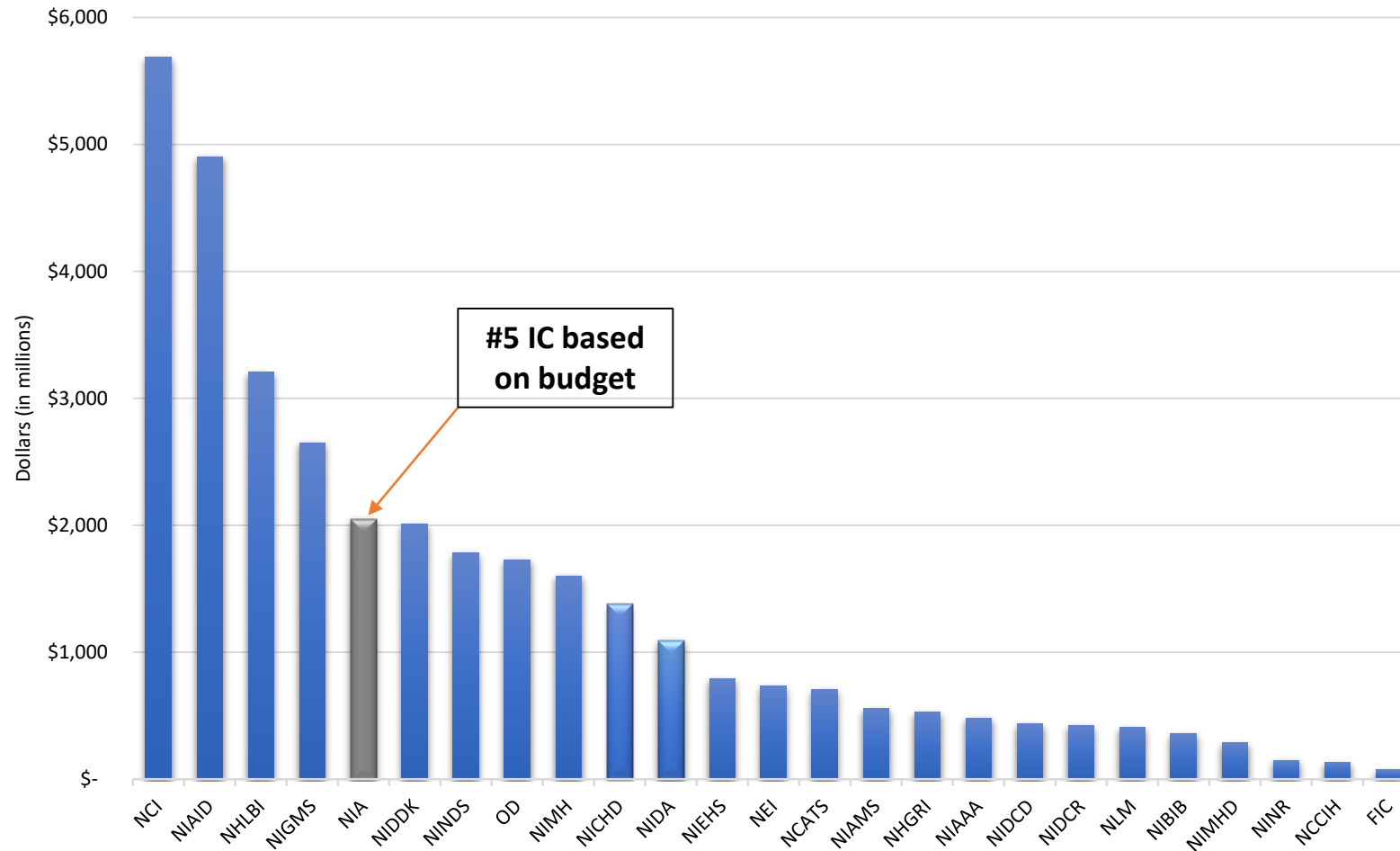
FY 2018 NIH Operating Plan Budgets

FY 2019 NIH Operating Plan Budgets

How are we preparing for the unknown?

- Regularly re-assessing our funding lines: https://www.nia.nih.gov/research/blog/2018/02/art-reading-tea-leaves

- Modeling the impact of using single-year funding vs multi-year funding under multiple appropriations scenarios:
  - How will commitments made now impact our future ability to support new competing awards?
  - Under what conditions might a "steady state" be reached?

- Improving efficiency with the release of a "Parent" FOA, including nine topics of research interest in AD/ADRD: https://www.nia.nih.gov/research/blog/2018/02/long-story-about-strange-way-publish-funding-opportunities-or-just-another

Total Budget vs. Extramural FTEs Percentage Change (NIA)

- % Change of Budget
- % Change of Extramural FTEs

109.1%

14.7%

Percentage Change

Fiscal Year (FY)

National Institutes of Health

External Federal Agencies (USA)

International Alzheimer's Disease Research Portfolio (IADRP)

Non-Profit Organizations (USA)

International Organizations
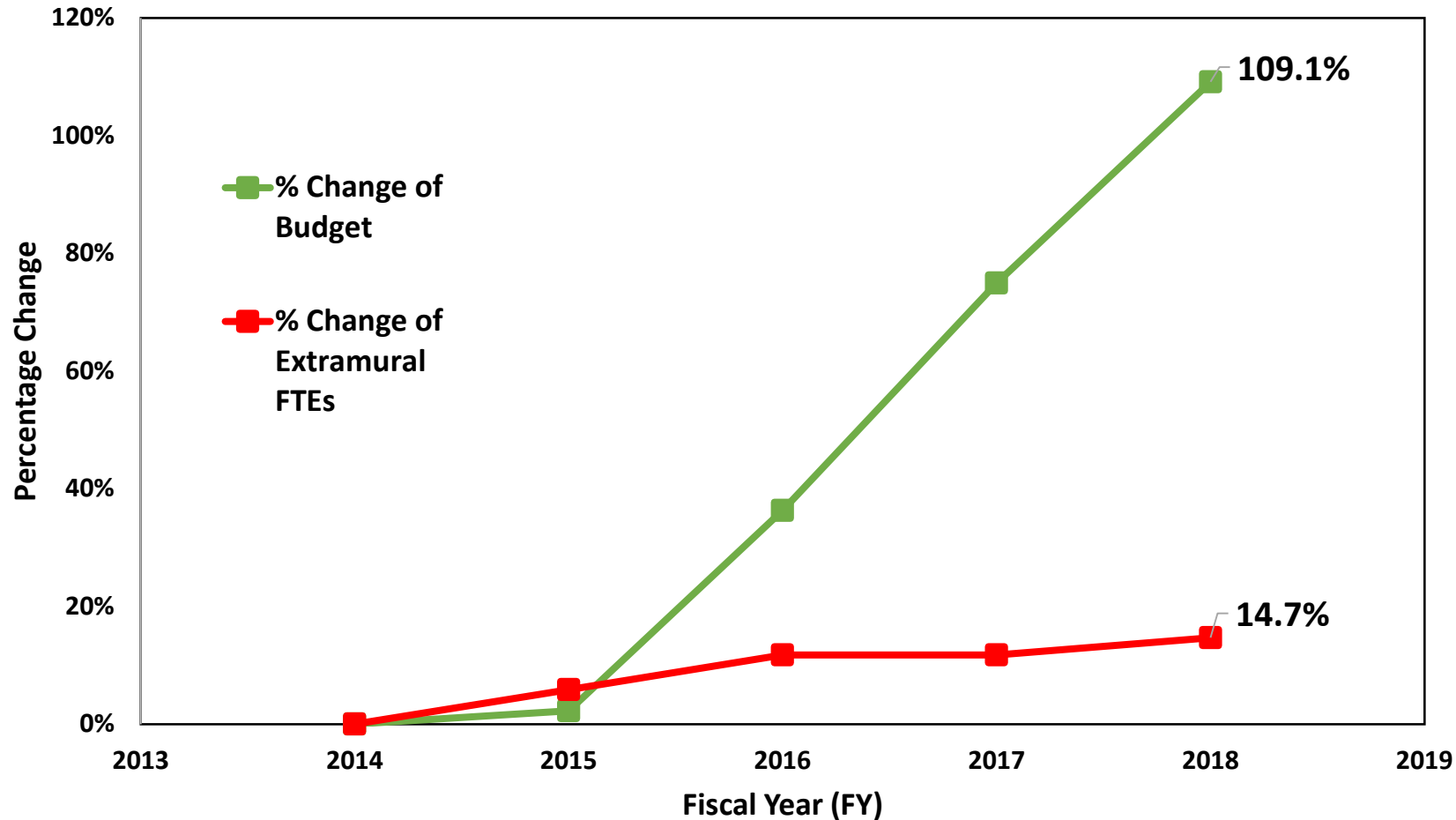
Over 8300 unique projects - 4200 funded by NIH

From more than 35 funding organizations across 11 countries

Diversity of AD/ADRD Research

Aging metabolic changes in AD

Comparative biology of neurodegeneration

Basic Biological Processes of AD

Geroscience

Biomarkers

Research on Disease Mechanisms

Research on Care and Caregiver Support

Cognitive outcomes in Population Studies

Alzheimer's Research

Disparities, Sex differences, and AD risk
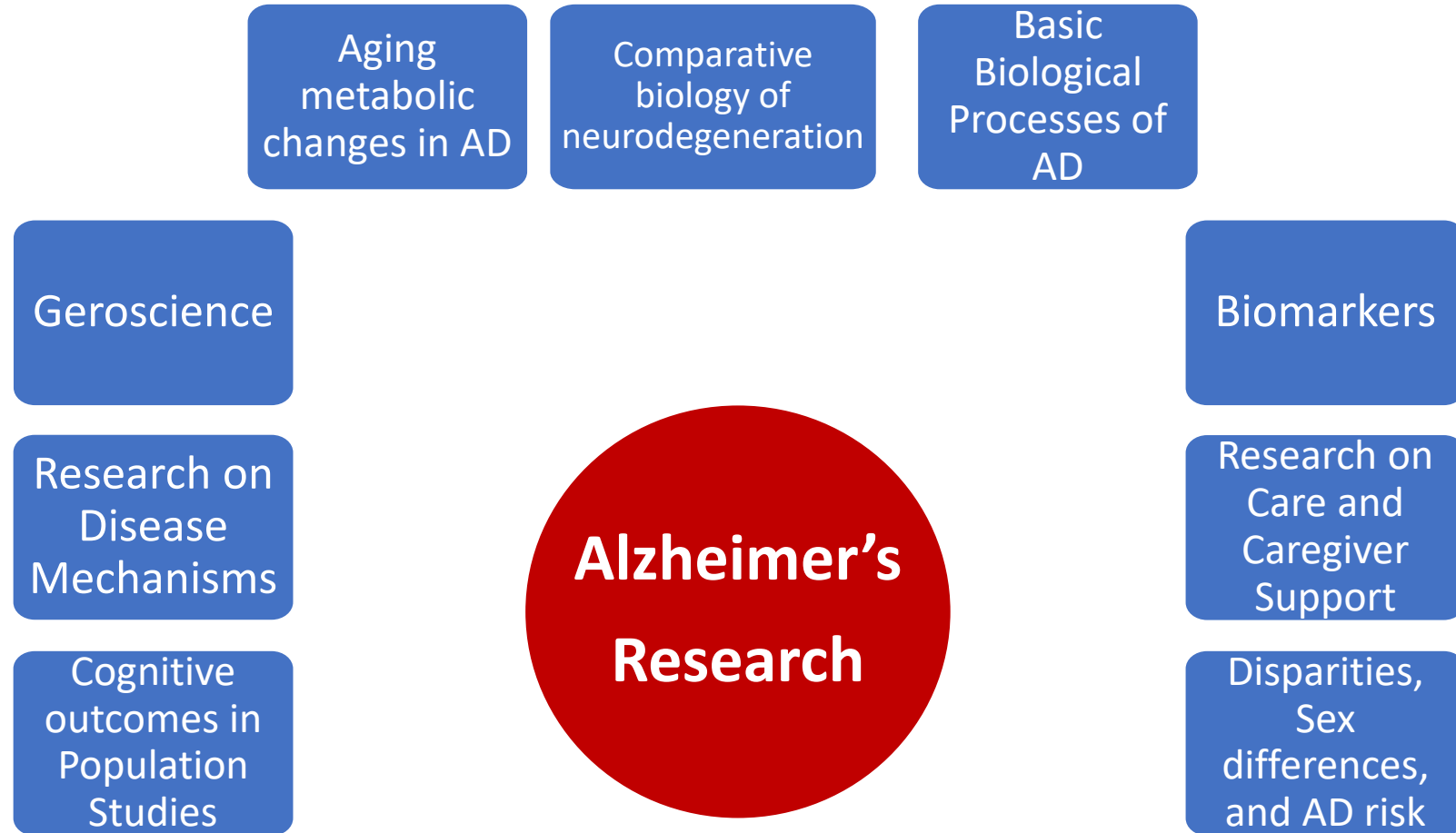
IADRP: FY 2017 Distribution of NIH's AD Research Projects across CADRO Categories

https://iadrp.nia.nih.gov/cadro-web/
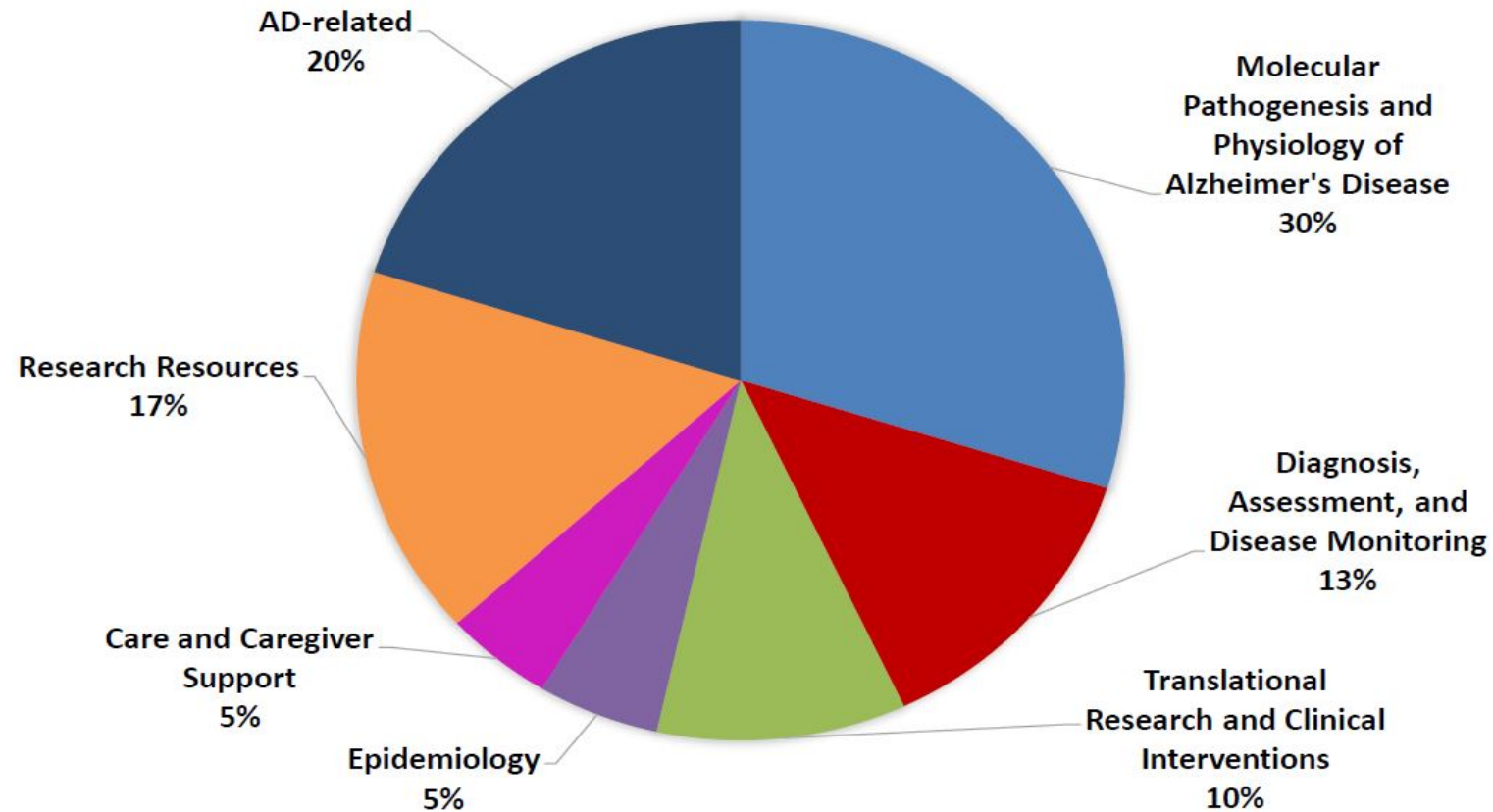
Competing AD and ADRD Research Investments FY 2014-2017
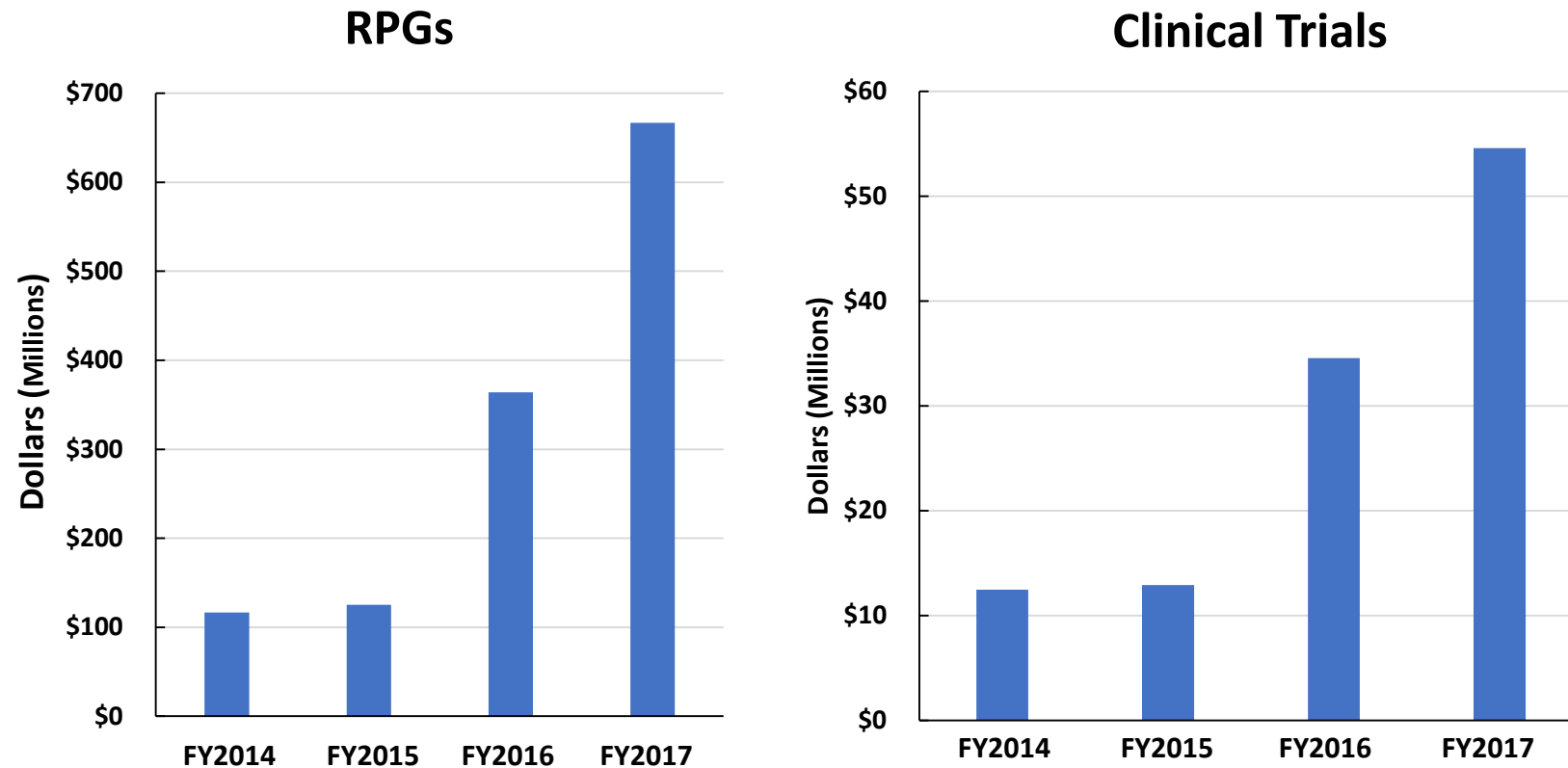
These figures show grants awarded with NIA funding. Some of the grants are in response to initiatives sponsored by NIH ICs other than NIA (e.g., NINDS, NIBIB, NIEHS, NIDCD).

AD/ADRD Awardees/NTF in FY 2017
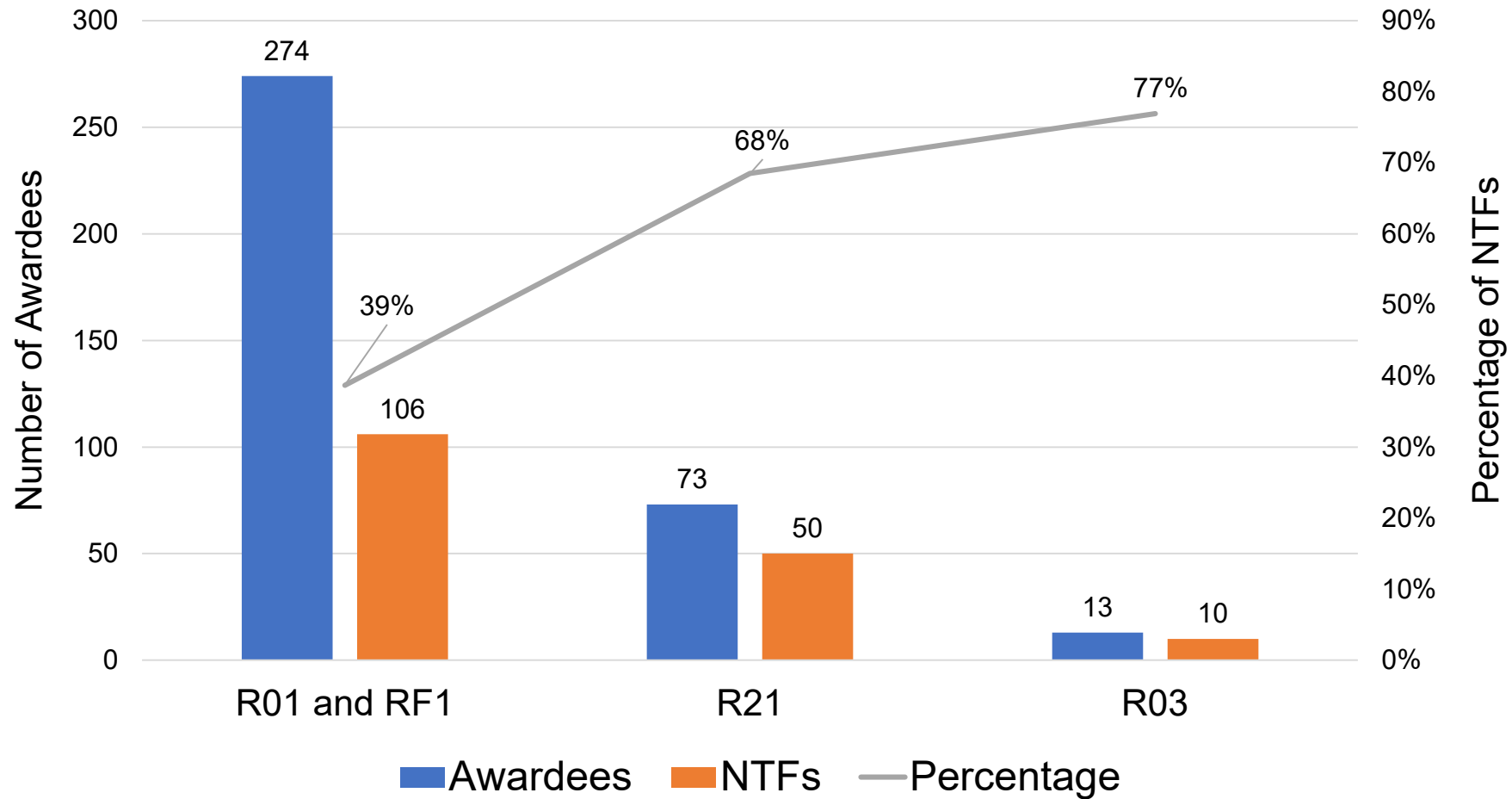
New to AD/ADRD Field (NTF): Investigator who never had any prior NIH AD/ADRD award/ application

Recruitment to a Growing AD/ADRD Workforce

~1/4 of NIA's Alzheimer's and related dementias awardees from Fiscal Year 2015-2018 were either *new or early stage* investigators

~1/3 of NIA's Alzheimer's and related dementias awardees were *new to the field*

Supplements by Institute/Center
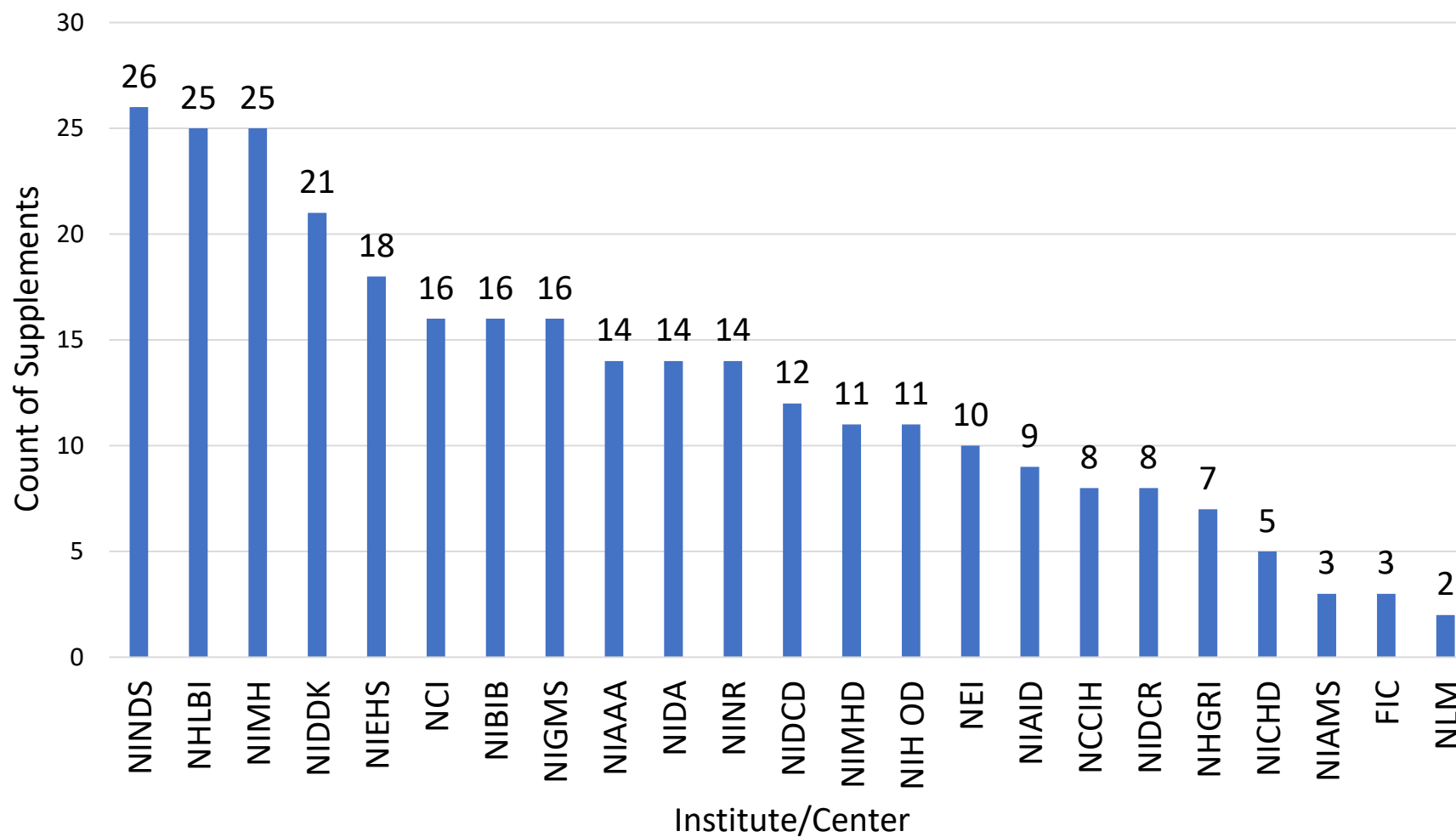
NIA Planning Post Appropriation for FY 2019

- Must be different tomorrow than we are today
- Revisit decisions made prior to Appropriation
- All hands on deck – break through organizational silos
- Must be used on additional AD relevant research – our call. And want a solid/justifiable definition of AD
- BI-Weekly AD meeting 5-7 in the evening.
- New committees to review:
  - Grants not initially coded as AD, but program thinks should be
  - Grants from other Institutes
- NIA internal processes
  - Information flow
  - New IT system to track and manage funding decisions
  - Documentation of decisions

How did we do in FY 2018?

MECHANISM	FY2018 Operating Plan Amount ($k)	FY 2018 Actual Amount ($k)	Balance ($k)
Research Grants:			
Research Projects:			
Noncompeting	$837,330	$846,439	-$9,109
Administrative Supplements	$177,078	$177,065	$13
Competing:			
Renewal	$113,892	$112,483	$1,409
New	$801,462	$791,547	$9,915
Supplements	$5,490	$5,422	$68
Subtotal, Competing	**$920,844**	**$909,452**	$11,392
Subtotal, RPGs	**$1,935,252**	**$1,932,956**	$2,296
SBIR/STTR	$87,296	$87,483	-$187
Research Project Grants	**$2,022,548**	**$2,020,439**	**$2,109**
Research Centers:			
Specialized/Comprehensive	$133,270	$133,824	-$554
Comparative Medicine	$567	$567	$0
Research Centers	**$133,837**	**$134,391**	**-$554**
Other Research:			
Research Careers	$45,085	$45,355	-$270
Other	$50,057	$50,906	-$849
Other Research	**$95,142**	**$96,261**	**-$1,119**
Total Research Grants	**$2,251,527**	**$2,251,091**	**$436**
Ruth L. Kirschstein Training Awards:			
Individual Awards	$6,210	$5,981	$229
Institutional Awards	$23,737	$24,622	-$885
Total Research Training	**$29,947**	**$30,603**	**-$656**
Research & Development Contracts	$78,986	$76,995	$1,991
SBIR/STTR (non-add)	*$175*	*$175*	$0
Intramural Research	$148,506	$148,566	-$60
Research Management and Support	$62,536	$64,183	-$1,647
Total, NIA	**$2,571,502**	**$2,571,438**	**$64**

FY 2018 Lapse: ~$64k

42

Payline Update FY 2019

CSR-reviewed Research Applications				
	General Payline, <$500k	General Payline, =>$500k	AD/ADRD Payline, <$500k	AD/ADRD Payline, =>$500k
All applications except as noted below	15	12	28	25
N.I. R01s	18	15	31	28
E.S.I. R01s	20	17	33	30

New investigator: *An applicant who has not received a prior R01 award or its equivalent.*
Early-Stage Investigator: *A new investigator who is within 10 years of finishing research training.*
First-time renewing; *A former new or early-stage investigator's first renewal application when the investigator has no other NIH grant support.*
ADRD: *Research on Alzheimer's Disease and on Alzheimer's Disease-related dementias*

Payline Update FY 2019 *cont'd*

NIA-reviewed Applications		
	General Payline	**AD/ADRD Payline**
Program projects (PO1)	20	38
Other NIA-reviewed research	20	38

Training-related Applications		
	General Payline	**AD/ADRD Payline**
Training grants (T32, T35)	*TBD*	*TBD*
Career awards	21	28
Fellowships	*TBD*	*TBD*

AD/ADRD & Non-AD Payline
All Applications Except N.I. or E.S.I. R01s
FY 2014-2019

Payline Percentage

Fiscial Year

— <$500k, Alzheimer's   — >=$500k Alzheimer's   — <$500k, General   — >=$500k General
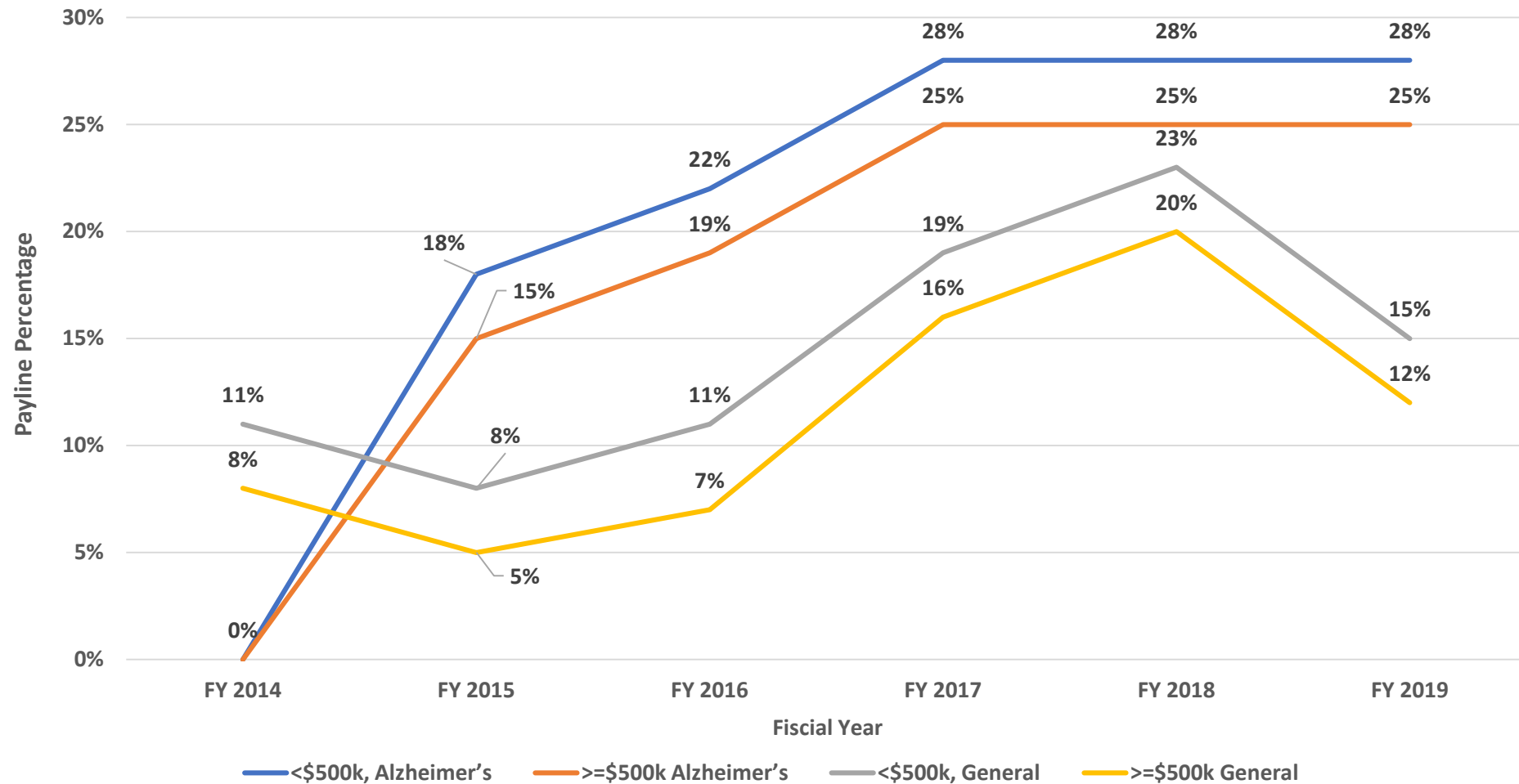
Bypass Budget Language

SEC. 230. Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall **prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer's Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer's Plan**, as required under section 2(d)(2) of Public Law 111–375.

AD Bypass Budget

- Language in SEC. 230 of the FY 2015 Appropriations Act requires a bypass budget for NIH Alzheimer's disease research to be submitted to the President.

- The HHS Secretary may review and comment, but not alter, the NIH budget submission.

- The budget will be estimated based on the NIH components of the National Alzheimer's Plan.

Trans-NIH Input for FY 2020 ADBB

Thirteen Institutes and Centers provided feedback that contributed to the development of this year's professional judgment budget:

NIA *(National Institute on Aging)*

NINDS *(National Institute on Neurological Disorders and Stroke)*

NIMH *(National Institute of Mental Health)*

NINR *(National Institute of Nursing Research)*

NIGMS *(National Institute of General Medical Sciences)*

NICHD *(National Institute of Child Health and Human Development)*

NIEHS *(National Institute of Environmental Health Sciences)*

NIDDK *(National Institute of Diabetes and Digestive and Kidney Diseases)*

NIDCR *(National Institute of Dental and Craniofacial Research)*

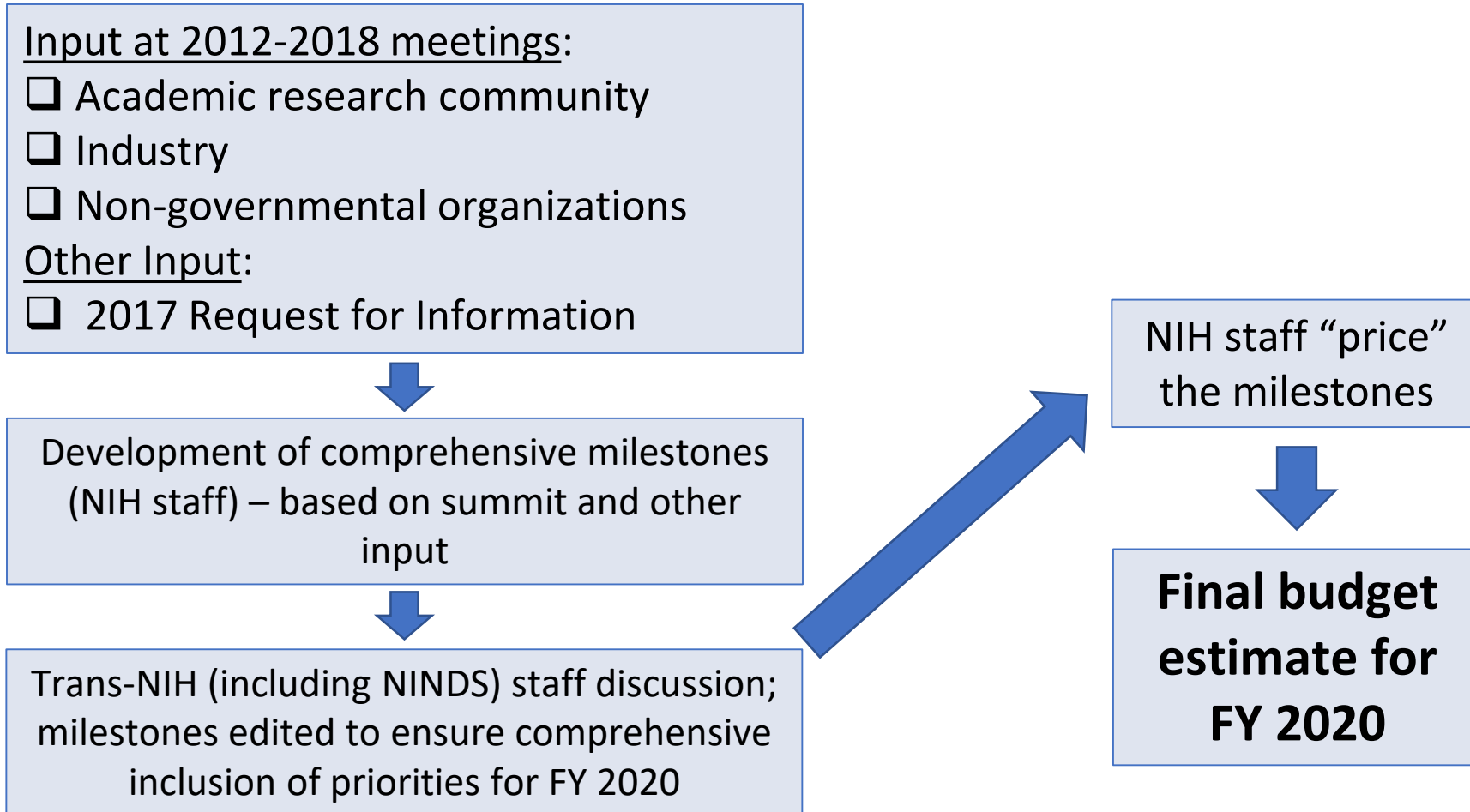**NHLBI** *(National Heart, Lung, and Blood Institute)*

NIAAA *(National Institute on Alcohol Abuse and Alcoholism)*

NCATS *(National Center for Advancing Translational Sciences)*

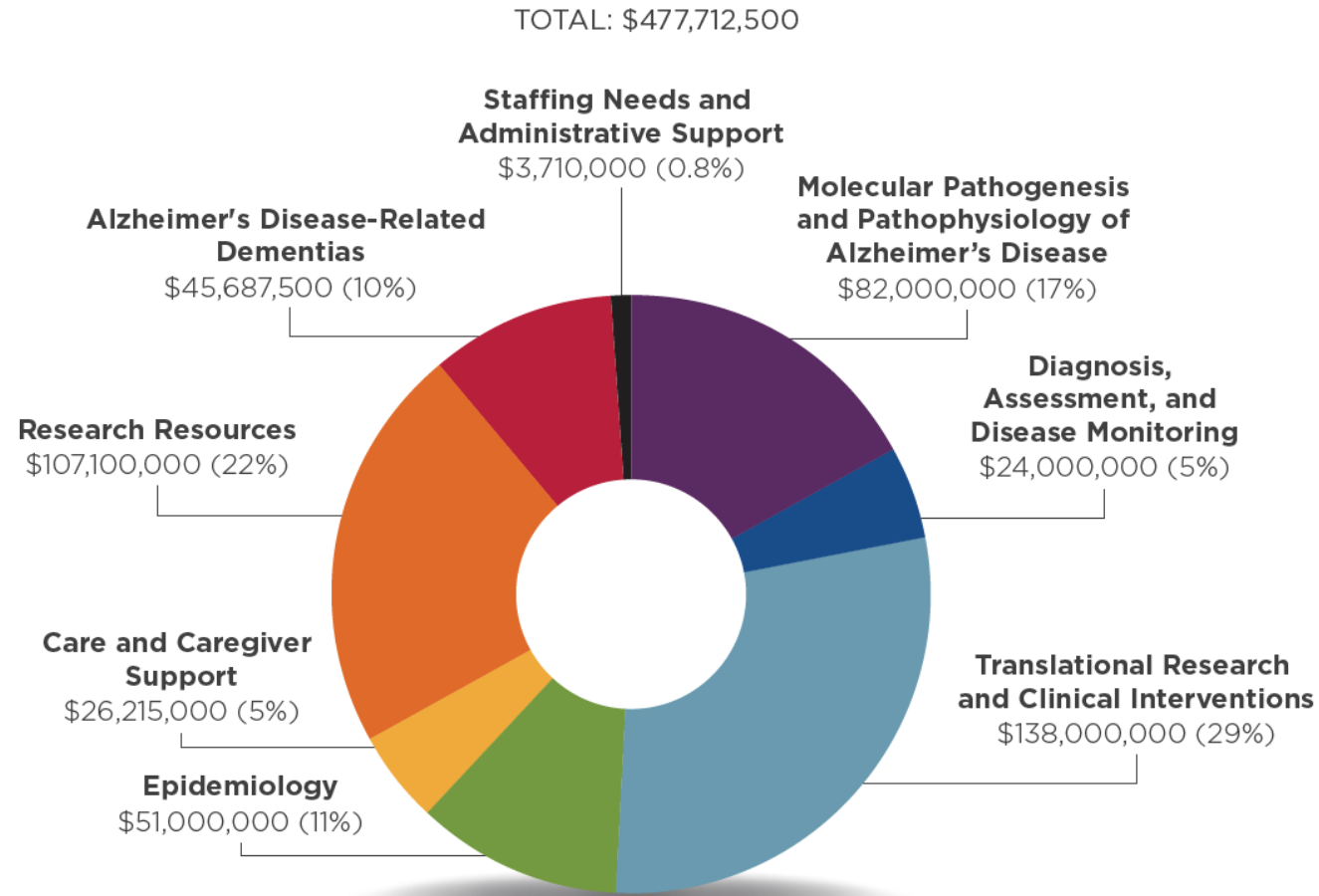**FIC** *(Fogarty International Center)*

Combined External and Internal Input – FY 2020 AD/ADRD Bypass Budget

Input at 2012-2018 meetings:
- ❑ Academic research community
- ❑ Industry
- ❑ Non-governmental organizations

Other Input:
- ❑ 2017 Request for Information

Development of comprehensive milestones (NIH staff) – based on summit and other input

Trans-NIH (including NINDS) staff discussion; milestones edited to ensure comprehensive inclusion of priorities for FY 2020

NIH staff "price" the milestones

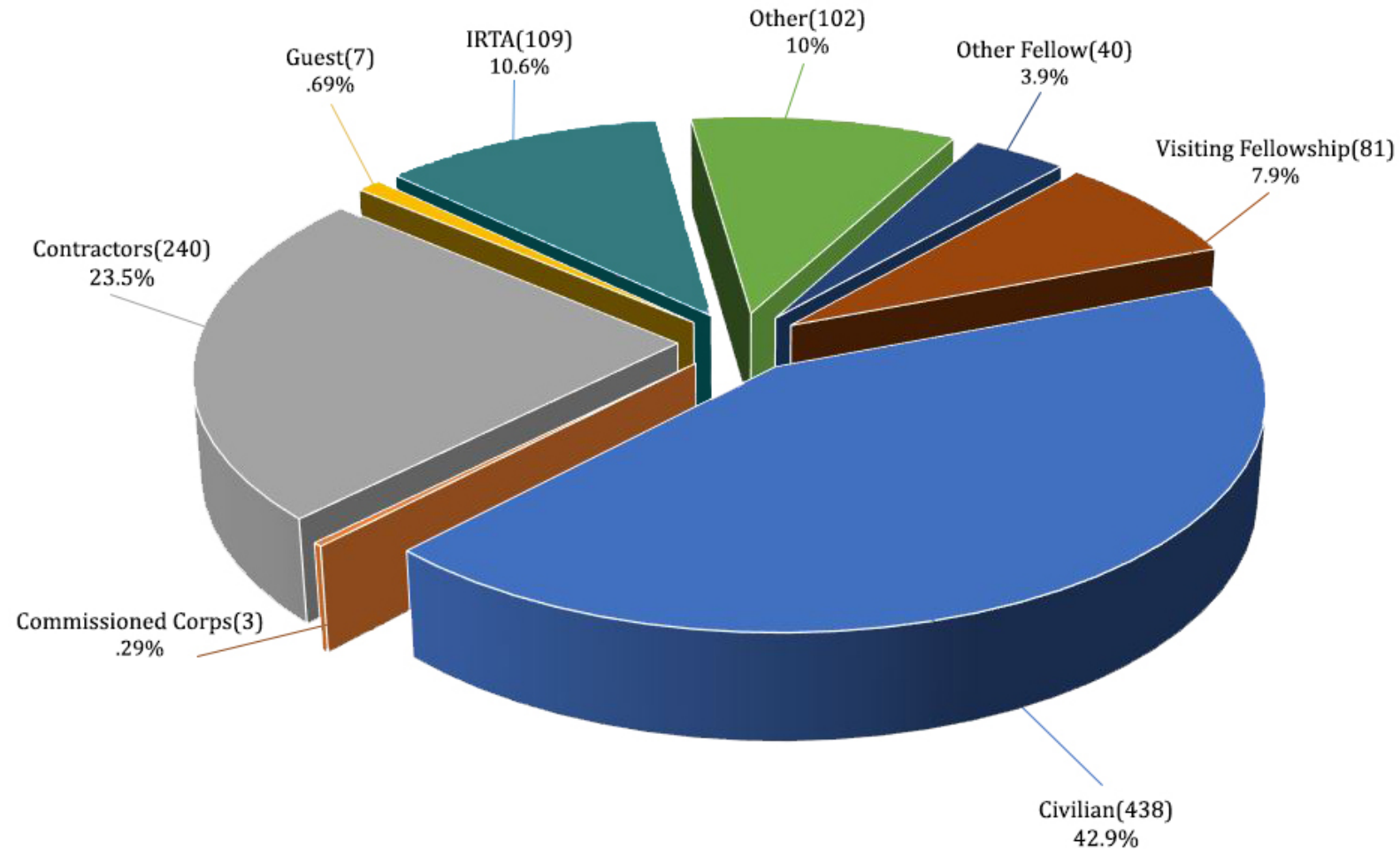**Final budget estimate for FY 2020**

FY 2020 Professional Judgment Budget

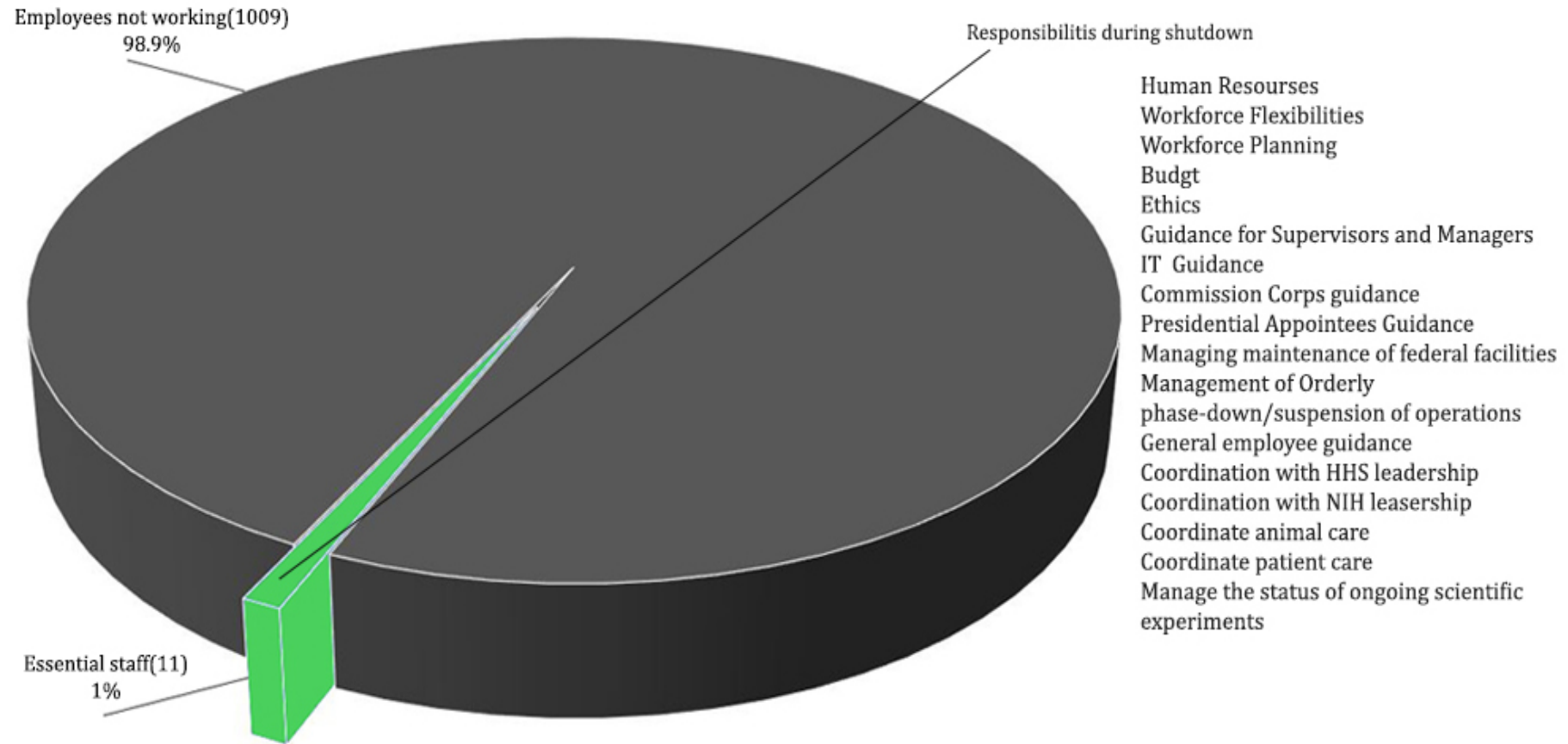| Area of Research	Amount (dollars in thousands)
A. Molecular Pathogenesis and Physiology of Alzheimer's Disease	$82,000
B. Diagnosis, Assessment and Disease Monitoring	$24,000
C. Translational Research and Clinical Interventions	$138,000
D. Epidemiology	$51,000
E. Care and Caregiver Support	$26,215
F. Research Resources	$107,100
H. Alzheimer's Disease-Related Dementias	$45,687
Staffing Needs, Support, and Misc.	$3,710
Total Additional Resources Needed	**$477,712**

Distribution of *Additional* Budget Funding Request Across Research Areas, FY 2020

TOTAL: $477,712,500

Staffing Needs and Administrative Support
$3,710,000 (0.8%)

Molecular Pathogenesis and Pathophysiology of Alzheimer's Disease
$82,000,000 (17%)

Alzheimer's Disease-Related Dementias
$45,687,500 (10%)

Diagnosis, Assessment, and Disease Monitoring
$24,000,000 (5%)

Research Resources
$107,100,000 (22%)

Translational Research and Clinical Interventions
$138,000,000 (29%)

Care and Caregiver Support
$26,215,000 (5%)

Epidemiology
$51,000,000 (11%)

1020 active NIA staff, before the 2018 shutdown

Guest(7) .69%

IRTA(109) 10.6%

Other(102) 10%

Other Fellow(40) 3.9%

Visiting Fellowship(81) 7.9%

Contractors(240) 23.5%

Commissioned Corps(3) .29%

Civilian(438) 42.9%

11 active NIA staff, during the 2018 shutdown

Employees not working(1009)
98.9%

Essential staff(11)
1%

Responsibilitis during shutdown

Human Resourses
Workforce Flexibilities
Workforce Planning
Budgt
Ethics
Guidance for Supervisors and Managers
IT Guidance
Commission Corps guidance
Presidential Appointees Guidance
Managing maintenance of federal facilities
Management of Orderly
phase-down/suspension of operations
General employee guidance
Coordination with HHS leadership
Coordination with NIH leasership
Coordinate animal care
Coordinate patient care
Manage the status of ongoing scientific
experiments

New AD Funding Opportunities

Ways to stay informed and connected

- **Visit**

  https://www.nia.nih.gov/research/funding

  to search all active NIA funding opportunities

- **Subscribe to our blog to stay up to date with the latest from NIA**

  https://www.nia.nih.gov/research/blog

Implementation Tracking

- **IADRP: http://iadrp.nia.nih.gov/**

  o Will continue to offer detailed tracking of initiatives and awards with respect to our research milestones, under the CADRO categories

- **Web-based tool for tracking funding initiatives and activities: https://www.nia.nih.gov/alzheimers/milestones**

  o Developed by the NIH and other AD funding organizations

  o Aimed at addressing the research milestones associated with NAPATracks funding initiatives and activities aimed at addressing the research milestones associated with goal one of the National Plan

  o Facilitates strategic coordination and collaborations

  o Spans the entire AD research landscape including basic, translational, clinical and health services research

Tracking Funding Opportunities

Funding Opportunity Announcements:

- **NIA Alzheimer's Disease and Related Dementias FOAs:**
  http://www.nia.nih.gov/AD-FOAs

- **Supplements to Other ICs:**
  https://grants.nih.gov/grants/guide/notice-files/NOT-AG-18-039.html

- **NINDS Alzheimer's Disease and Related Dementias FOAs:**
  https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Translational-Research

Additional Resources:

- **Follow our "Inside NIA" blog:**
  https://www.nia.nih.gov/research/blog

Ongoing NIA AD/ADRD and Related Intervention and Prevention Trials (~140)

29 Early-stage Clinical Drug Development (Phase I and Phase II Clinical Trials)	6 Late-stage Clinical Drug Development (Phase II/III and Phase III Clinical Trials)	53 Non-Pharma-cological Interventions	7 Clinical Therapy Development for the Neuro-psychiatric Symptoms of AD/ADRD	39 Care and Caregiver Interventions	3 Delirium/Post-Operative Cognitive Decline Trials

Amyloid (8)
Receptors (4)
Metabolism and Bioenergetics (4)
Vasculature (3)
Growth Factors and Hormones (1)
Multi-target (6)
Oxidative Stress (2)
Other (1)

Amyloid (5)
Vasculature (1)

Exercise (13)
Diet (5)
Cognitive Training (14)
Combination Therapy (7)
Other (14)

Pharmacological (5)
Non-Pharmacological (2)

Philanthropy is playing a role

https://www.gatesnotes.com/Health/Digging-Deep-Into-Alzheimers

https://www.gatesnotes.com/Health/A-better-way-of-diagnosing-Alzheimers

https://www.gatesnotes.com/Health/The-unexpected-way-we-might-one-day-diagnose-Alzheimers

Thank You

Questions?

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