In Memoriam

Paul Greengard, Ph.D.
1925 -- 2019
Nobel laureate and neurobiologist at Rockefeller University who is best known for his work showing that the brain not only communicates with electrical signals but also with chemicals such as dopamine.

Gavril W. Pasternak, M.D., Ph.D.
1947 -- 2019
Internationally recognized scientist from Memorial Sloan Kettering whose research helped to shape current knowledge of opioid receptors and pharmacology.
<table>
<thead>
<tr>
<th></th>
<th>FY 2018 Actuals</th>
<th>FY 2019 Enacted</th>
<th>FY 2020 PB</th>
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<tbody>
<tr>
<td><strong>NonAIDS</strong></td>
<td>$854,609,000</td>
<td>$893,402,000</td>
<td>$796,379,000</td>
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<tr>
<td><strong>AIDS</strong></td>
<td>$269,765,000</td>
<td>$264,814,000</td>
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<tr>
<td><strong>Total</strong></td>
<td>$1,124,374,000</td>
<td>$1,158,216,000</td>
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<tr>
<td><strong>Opioids</strong></td>
<td>$250,000,000</td>
<td>$250,000,000</td>
<td>$250,000,000</td>
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National Institute on Drug Abuse Portfolio
Annual Appropriation
FY 2018 Actual

- Division of Neuroscience & Behavior -- 41%
- Division of Epidemiology, Services & Prevention Research -- 28%
- Division of Therapeutics and Medical Consequences -- 14%
- Center for the Clinical Trials Network -- 4%
- RMS -- 6%
- Intramural Research -- 8%
Cannabis Laws in United States

- **Legal**
- **Legal medical use**
- **Legal medical use, limited THC content**
- **Prohibited**

Cannabis Potency (% Δ-9 THC)

Potency Quadrupled in Past 20 Years

Source: Potency Monitoring Program, Quarterly report Number 139, NIDA Contract Number: No1DA-15-7793
Adolescent Brain Cognitive Development (ABCD) Study

ABCD Study Fast Track Neuroimaging Data
https://data-archive.nimh.nih.gov/abcd

FullBaseline Curated Data Released
Data on 11,875 participants was released in April 2019, including:
- Basic demographics,
- Assessments of, physical and mental health, substance use, culture and environment, and neurocognition,
- Tabulated structural and functional neuroimaging data,
- Minimally processed brain images,
- Biological data (e.g., pubertal hormone analyses),
- Genotypic data from the Smokescreen array
- Residential history derived data (e.g., crime, area deprivation index, walkability, population density, pollution)

Data Exploration and Analysis Portal (DEAP)
DEAP provides the means to find measures of interest from more than 40,000 shared observations available for each ABCD participant, to test hypotheses using a multi-level regression model suitable for the ABCD study design, and to run novel multi-level statistical analysis directly from the DEAP interface.
OVERDOSE FATALITIES

EVOLUTION OF THE OPIOID CRISIS

Source: Centres for Disease Control and Prevention
Trajectories to Opioid Misuse, Addiction and Overdoses

Opioid Addiction and Overdoses

1. Opioid Prescription for Pain
2. Misuse of Opioid Prescription

1. Pain patient who transitions to heroin
2. Px Opioid misuser who transitions to heroin
3. Initiates with Heroin
4. Transitions from heroin to fentanyl and other synthetic drugs

HELPING END ADDICTION LONG TERM SM (HEAL)

1. Prevent Chronic Pain
2. Improve Treatment of Chronic Pain
3. Prevent Opioid Addiction
4. Prevent Opioid Overdoses
5. Treatment of Opioid Addiction to Achieve Recovery
EXPAND THERAPEUTICS FOR OUD AND OD

RFA DA-19-002: Development of Medications to Prevent and Treat OUD and Overdose

**Actions to Date:**
- 5 cycles of reviews (since May, 2018)
- Rolling acceptance of applications
- Length of time between receipt to approval shortened from 9 months to < 2 months

**Recent Actions:**
February 21, 2019 – 4th cycle applications reviewed
April 1, 2019 – 5th cycle applications received

**Future Plans:**
July 1, 2019 -- Next due date
NIDA will launch a new Council Workgroup
Therapeutic Development for SUD

Charge:

• To provide scientific input on the current and future research portfolio for NIDA’s Division of Therapeutics and Medical Consequences.
• To provide input on the development of medications and devices to treat SUD and review concepts and recommend emerging pharmacotherapies, behavioral therapies and devices to treat SUD.

Chair: Kalpana M. Merchant, Ph.D.
Chief Scientific Officer
Vincere Biosciences, Inc.

David McKinzie, Ph.D.
Professor
Pharmacology & Toxicology
Director
Behavioral Phenotyping Core
Indiana University School of Medicine

Lisa Gold, Ph.D. (invited)
Consultant
Global Director (retired)
Scientific Affairs-Neuroscience
Merck

Chris Schmidt, Ph.D.
Research Fellow (retired)
Pfizer
✓ OUD is a treatable chronic brain disease

✓ FDA-approved medications to treat OUD are effective and save lives

✓ Long-term retention on MOUD is associated with improved outcomes

✓ A lack of availability of behavioral interventions is not justification to withhold MOUD

✓ Most people who could benefit from MOUD do not receive it, and access is inequitable

✓ Withholding or failing to have available all classes of FDA-approved MOUD in any care or justice setting is denying appropriate medical treatment

✓ Confronting the major barriers to use of MOUD is critical to addressing the opioid crisis

Sponsors: National Institute on Drug Abuse (NIDA)  
Substance Abuse and Mental Health Services Administration (SAMHSA)
Number Of Substance Abuse Treatment Facilities Offering Any MAT

Data Source: Substance Abuse and Mental Health Services Administration.

2004 National: 1027

2019 National: 5,941

Accessed: May 11, 2019

Management Of Subsyndromal OUD (12 Million Americans Misuse Opioids; How Do We Treat Them?)

Improving MOUD Retention (Personalizing Interventions)

Optimal Length Of MOUD?

Rural interventions

Opioid registry in diverse healthcare delivery system
CTN Council Workgroup

**Charge:**
- Provide scientific input and recommendations for current and future research projects of NIDA’s Clinical Trials Network (CTN)

**Chair:** Carlos del Rio, M.D.
Professor and Chair
Hubert Department of Global Health Rollins
School of Public Health
Emory University

**Co-Chair:** Hillary Kunins, M.D. Ph.D.
Assistant Commissioner
NYC Department of Health and Mental Hygiene
Clinical Professor
Albert Einstein College of Medicine

**Barbara Cimaglio, BA**
Project Director
Access to Medication-Assisted Treatment
Division of Substance Use Prevention and Recovery
Illinois Department of Human Services

**Dennis McCarty, Ph.D.**
Professor
Department of Public Health and Preventive Medicine
Oregon Health & Science University
OPTIMIZE EFFECTIVE TREATMENT STRATEGIES: JUSTICE AND COMMUNITY OPIOID NETWORK (JCOIN)

Reviewed
• Clinical Research Centers,
• Methodology Centers and
• Coordinating Centers

Future Plans:
• MOU with BJA to finalize June/July 2019
• Anticipated award dates:
  June 15, 2019 -- MAARC/CTC
  July 1, 2019 -- Clinical Research Centers
• Kickoff Meeting: September 25 -27, 2019
The HEALing Communities Study: Integrating Evidence Based interventions across Settings

**Healthcare**
- Primary care
- Emergency departments
- Inpatient hospital care
- Behavioral health

**Criminal Justice**
- Jails
- Prisons
- Parole/Probation
- Drug courts

**Community**
- Families
- Schools
- Police and fire departments
- Faith-based organizations
- Local industry
Overdose Rates per 100,000 Population (age-adjusted) in Research Site States

Source: Kaiser Family Foundation
Overdose Death Rates: Psychostimulants (Including Methamphetamine)

Centers for Disease Control and Prevention
Drug Overdose Deaths Involving Psychostimulants (Mainly Methamphetamine), by Opioid Involvement

Centers for Disease Control and Prevention, December, 2018.

Methamphetamine and Morphine Combination Increase Lethality >70% in Mice

HIV and HCV: Another Consequence of Opioid Epidemic

• HIV Prevention Trials Network: Approved protocol, INTEGRA: A Vanguard Study of Integrated Strategies for Linking Persons with OUD to Care and Prevention for Addiction, HIV, HCV, and Primary Care

• PrEP for HIV Prevention among Substance Using Populations—Approved concept

• RFA-DA-19-003: Molecular Regulation of Persistent HIV in Individuals with SUD
Social Interaction Preferred Over Heroin and Methamphetamine

Venniro et al., 2018

Rats given a choice, choose social interactions over Heroin or Meth but when stressed (shock) then heroin or Meth choices increase.