

National Institutes of Health Update

Council of Councils

January 26, 2018



Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH



Topics for Today

- Budget Update
- NIH Response to Opioid Crisis
- Data Science Update
- *Relmagine HHS... Optimize NIH*

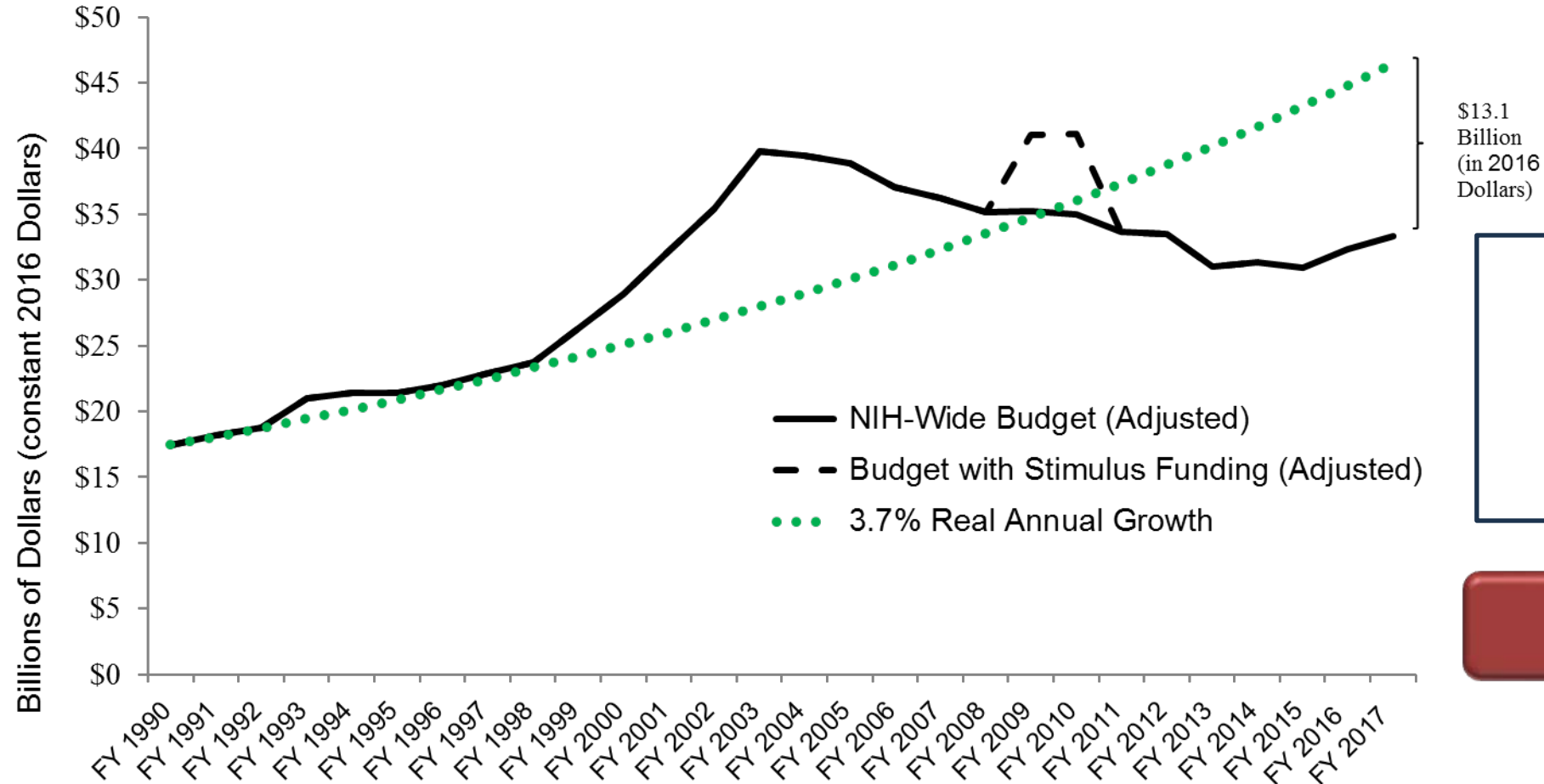


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National Institutes of Health Funding 1990-2017



C.R.	-\$0.3 B
House	+\$1.1 B
Senate	+\$2.0 B

Stay tuned!

Note: The 3.7% Real Annual Growth is based on real compound annual growth between 1971 and 1997. Dollar values are adjusted to 2016 dollars using the Biomedical Research and Development Price Index (BRDPI), <https://officeofbudget.od.nih.gov/gbiPriceIndexes.html>.

Source: NIH Office of Extramural Research and Office of Budget source data (January 19, 2017)

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Pain Facts

- Pain is the most common reason for seeking medical care
- Individuals with severe pain had worse health, used more health care, and had more disability than those with less severe pain
- Pain is associated with a wide range of injury and disease, and is sometimes the disease itself
- Some conditions may have pain and associated symptoms arising from a discrete cause, such as postoperative pain or pain associated with a malignancy, or may be conditions in which pain constitutes the primary problem, such as neuropathic pains or headaches
- The precise mechanisms underlying the transition from acute to chronic pain remain unresolved

Pain Facts

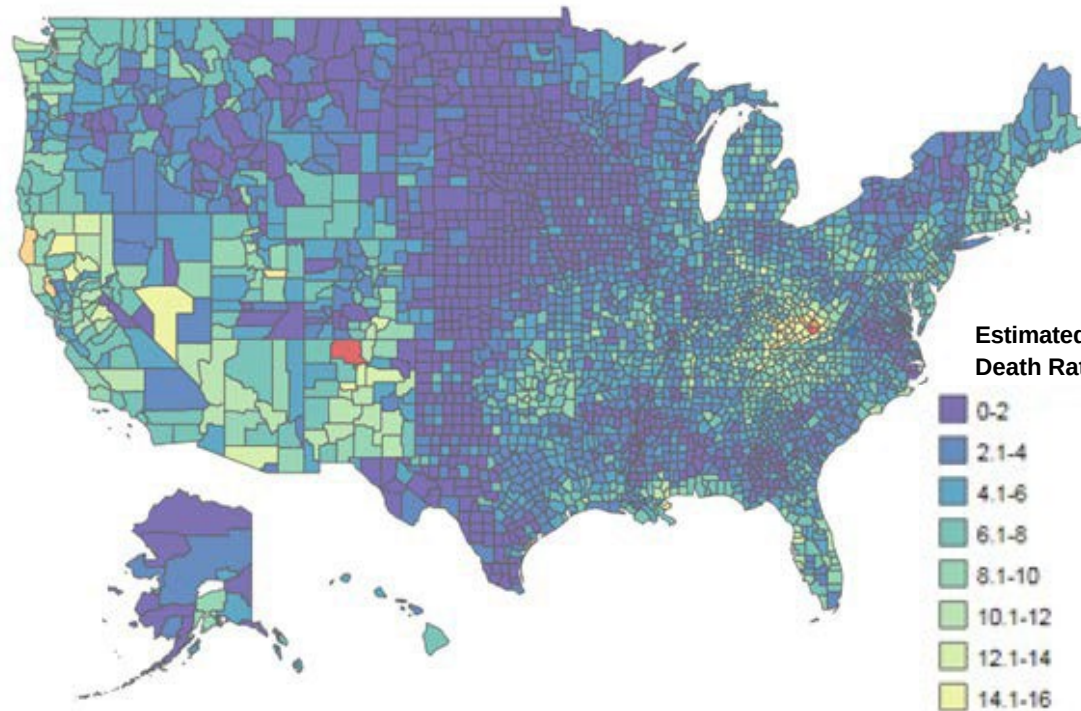
- About 25.3 million U.S. adults (11.2 percent) had pain every day for the previous 3 months
- Nearly 40 million adults (17.6 percent) had severe pain
- Pain costs society at least \$560-\$635 billion annually (in 2010 dollars) in the United States, which combines the medical costs of pain care and the economic costs related to disability days and lost wages and productivity

Challenges of the Opioid Epidemic

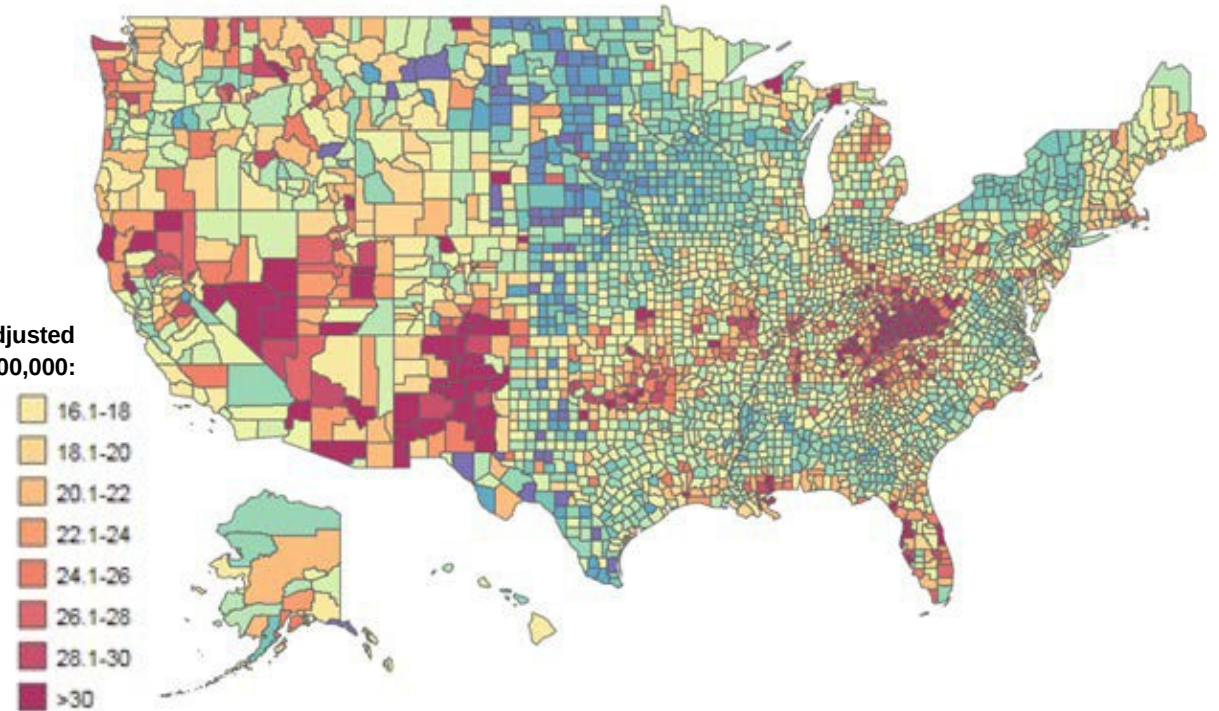
- 25.5 million adults have pain every day
 - Opioids are overprescribed, not effective for chronic pain
- More than 2 million Americans are addicted to opioids
 - Most started with prescription medicines
- Medication Assisted Treatment (MAT) is available for opioid use disorders and to prevent/reverse overdose
 - But MATs are drastically underutilized
 - Duration of treatment needed is not well understood
- Research has revolutionized our understanding of addiction and pain
 - But alternatives to treat addiction and overdose are limited
 - And new, non-addictive pain medicines are urgently needed

The Opioid Crisis: Overdose Death Rates

1999

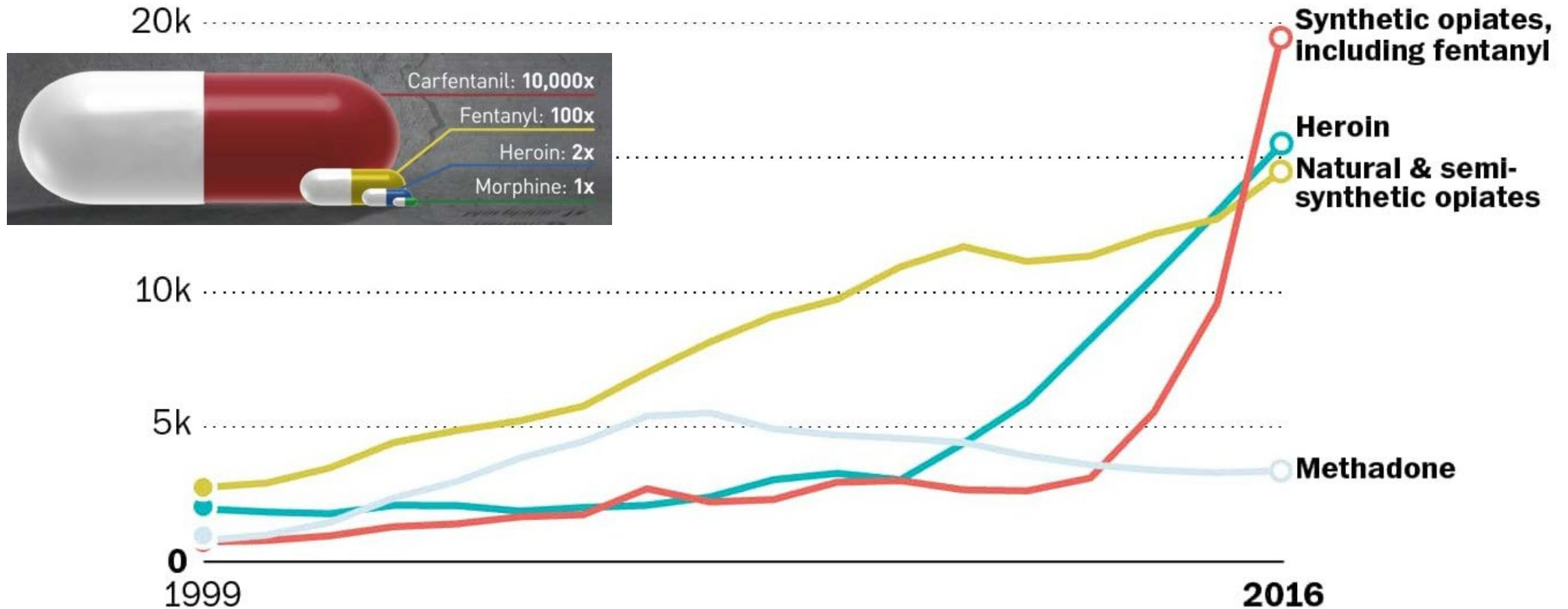


2015



Opioid deaths surge in 2016

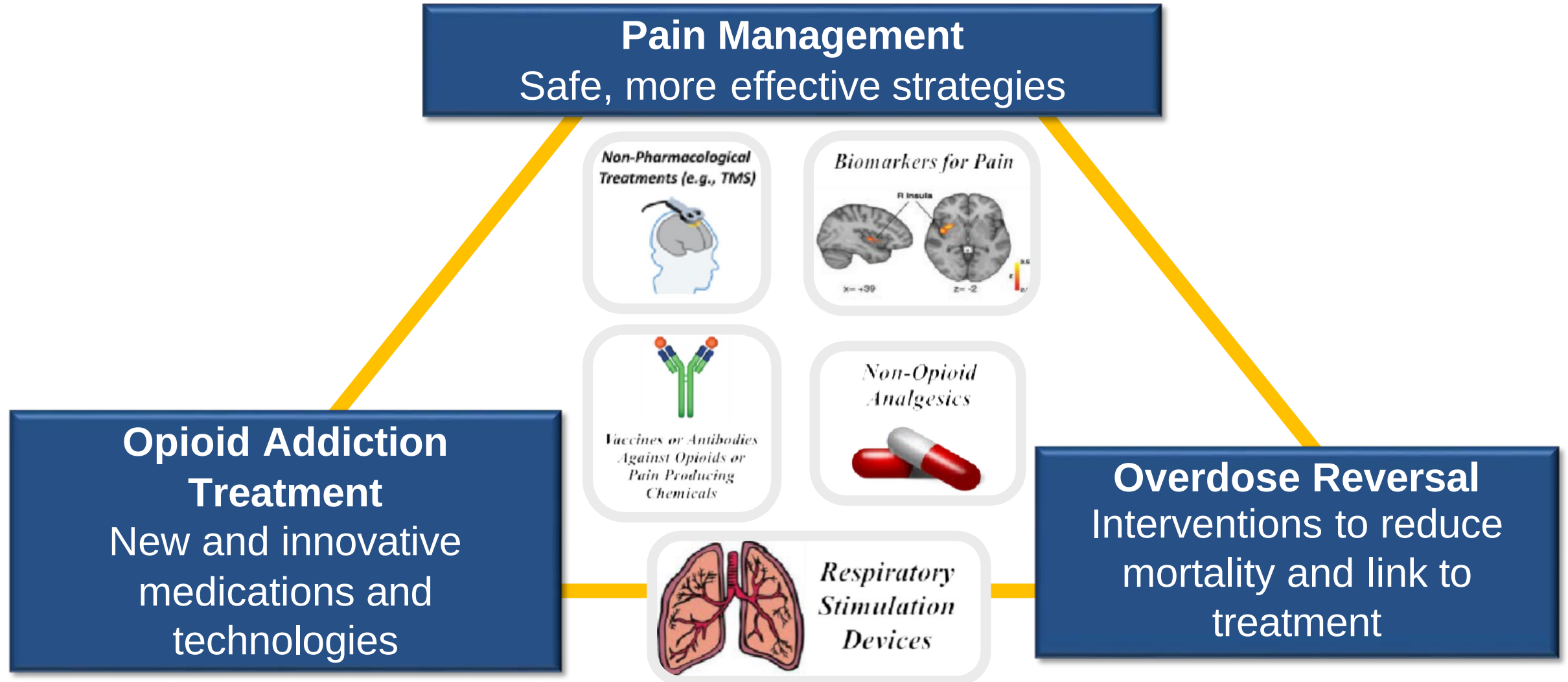
Number of opioid overdose deaths by category, 1999 to 2016



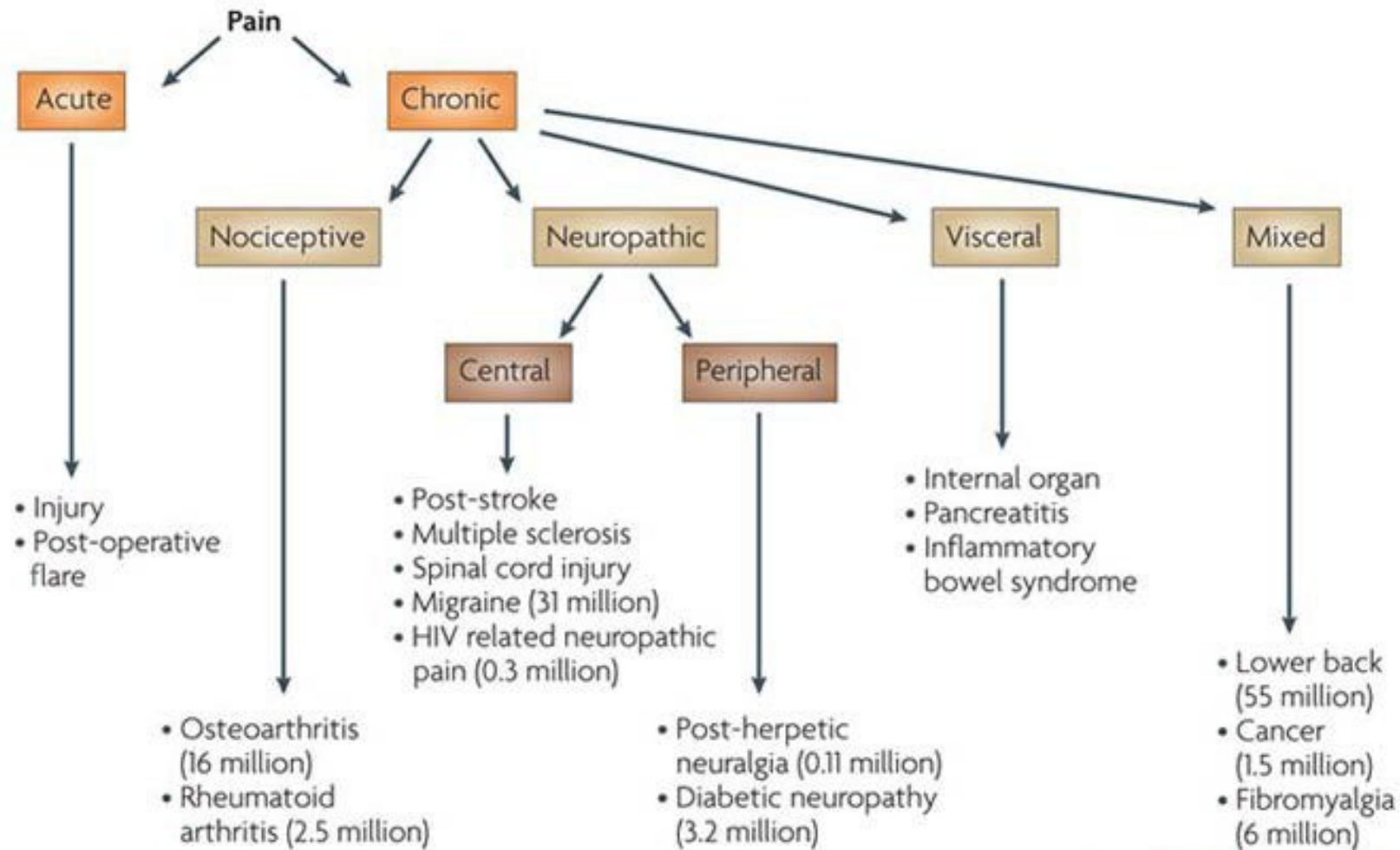
Over 42,000 opioid overdose deaths in 2016

NIH Opioid Research Initiative

Using Research to Help End the Opioid Crisis



Heterogenous Nature of the Patient Population



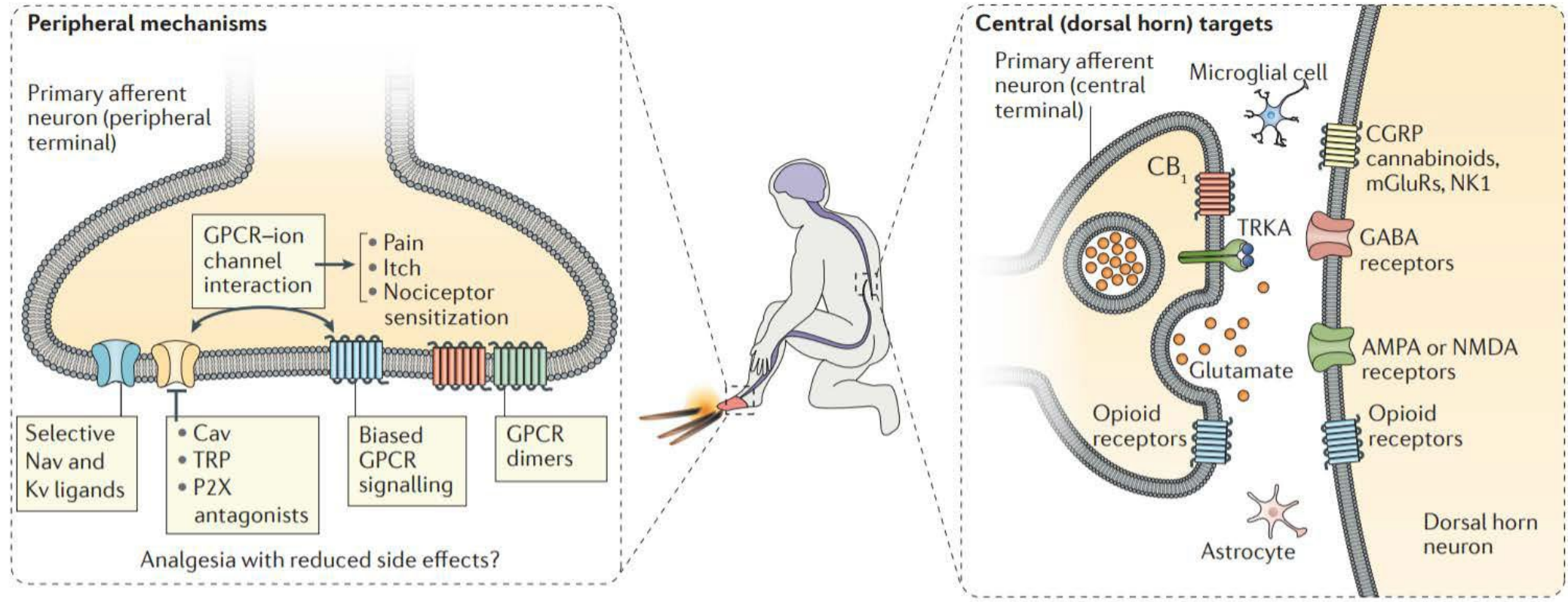
Investigators Are Identifying New Targets for Pain Therapy Development

NATURE REVIEWS | DRUG DISCOVERY

VOLUME 16 | AUGUST 2017

Breaking barriers to novel analgesic drug development

Ajay S. Yekkirala¹⁻³, David P. Roberson¹⁻³, Bruce P. Bean¹ and Clifford J. Woolf^{1,2}

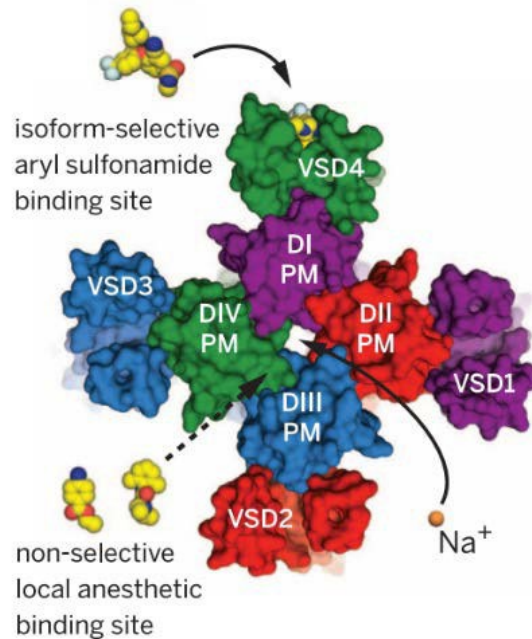


Some Exciting NIH-Supported Advances

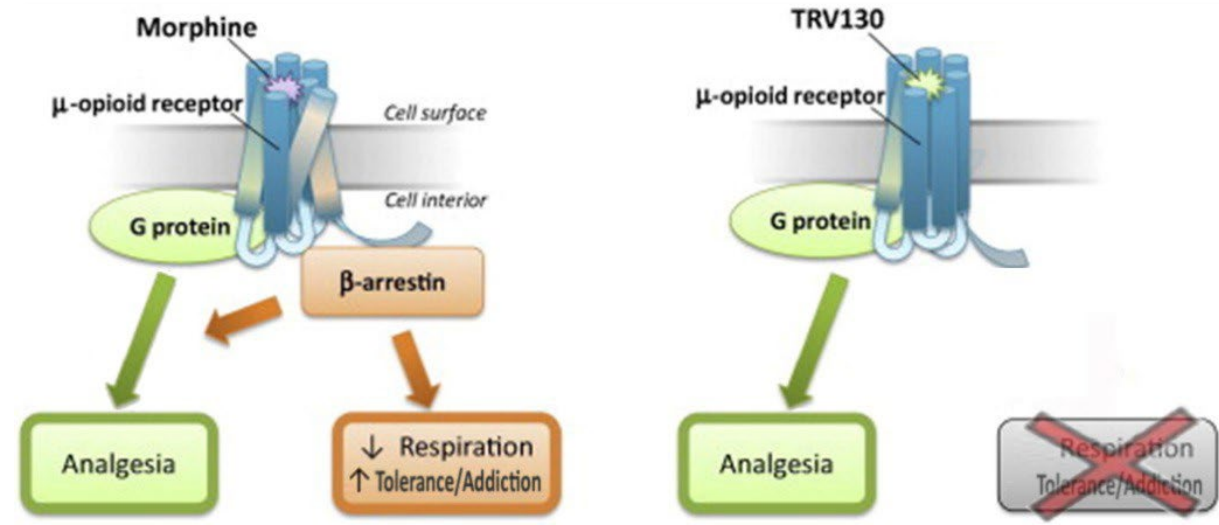
NATURE|Vol 444|14 December 2006

An *SCN9A* channelopathy causes congenital inability to experience pain

James J. Cox^{1*}, Frank Reimann^{2*}, Adeline K. Nicholas¹, Gemma Thornton¹, Emma Roberts³, Kelly Springell³, Gulshan Karbani⁴, Hussain Jafri⁵, Jovaria Mannan⁶, Yasmin Raashid⁷, Lihadh Al-Gazali⁸, Henan Hamamy⁹, Enza Maria Valente¹⁰, Shaun Gorman¹¹, Richard Williams¹², Duncan P. McHale¹², John N. Wood¹³, Fiona M. Gribble² & C. Geoffrey Woods¹



Na_v1.7



Evaluating Treatment Options for Patients with Chronic Low Back Pain



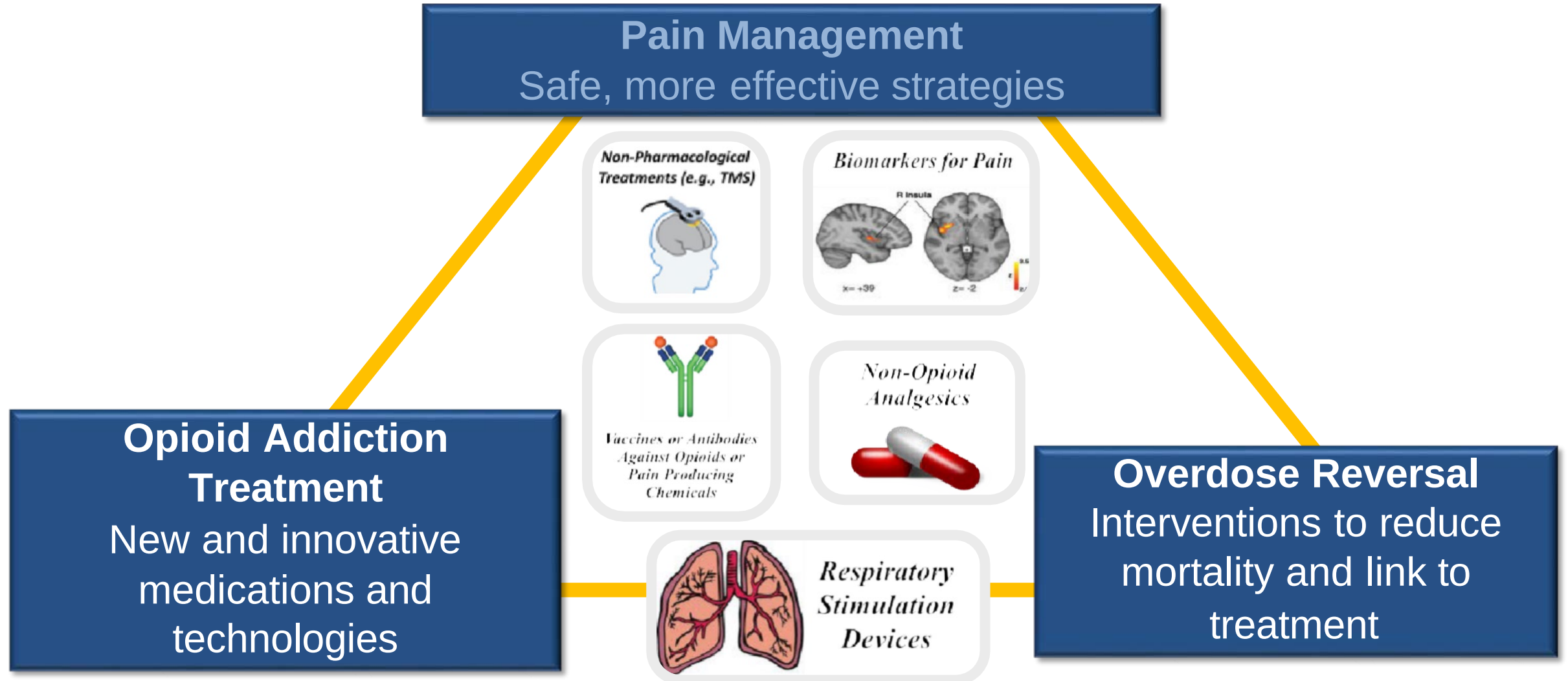
Funding/Support: Research reported in this article was supported by the National Center for Complementary and Integrative Health (NICCIH) of the National Institutes of Health (NIH) under award number RO1AT006226.



- Mindfulness-based stress reduction (MBSR) therapy and cognitive behavioral therapy both provided better results than usual care
- MBSR may be an effective treatment option for chronic low back pain

NIH Opioid Research Initiative

Using Research to Help End the Opioid Crisis



Some Successful NIH-Supported Interventions

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Case for a Public-Private Partnership on Medications for Opioid Use Disorder and Pain

- Urgent public health crisis
- Need for better alternatives for treatment of addiction
- Need for more potent treatments for overdose
- Absence of highly potent alternatives to opioids for pain
- Emergence of numerous potential drug targets
- Possibility of development/validation of biomarkers for pain relief
- Strong support at highest level of U.S. Government

Proposed Projects: Addiction and Overdose

- Focused Medication Development:
 - Partner companies with expertise in extended release and other delivery options with those with active OUD medication programs.
 - Identify potential new uses for existing or abandoned medications for other indications.
- Develop more potent or longer lasting opioid antagonists to reverse overdoses from fentanyl or its derivatives:
 - Identify industry groups with opioid antagonists and pharmacological expertise in extending receptor occupancy
 - Other targets for reversal of respiratory depression
- Collaborate with FDA to validate additional endpoints for opioid use disorder treatments

Proposed Projects: Pain

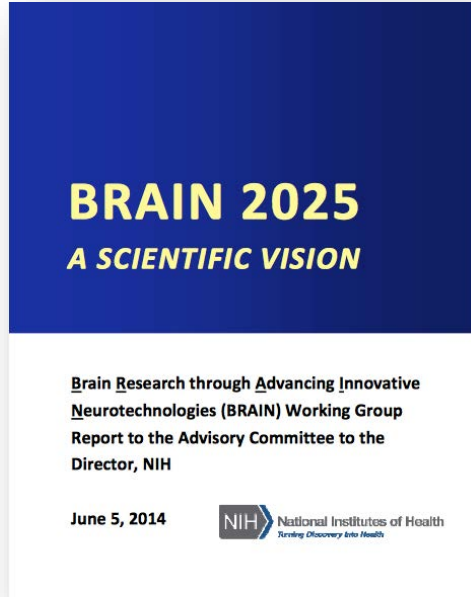
Accelerate the pathway to product registration for non-addictive pain Rx

- Develop a data sharing and asset repurposing consortium across industry, with NIH as neutral broker
- Establish a clinical research network to accelerate phase 2 trials, biomarker validation, clinical endpoint development/testing & regulatory processes
 - Early focus on more homogenous cohorts with severe unmet treatment needs
 - “rare disease” model to establish efficacy, potentially with follow-on trials to expand to larger cohorts
- Develop and validate biomarkers in specific pain conditions!
 - To distinguish subset of pain patients by phenotype or biologic mechanism
 - To document target engagement relevant to pain subtype and/or drug mechanism of action
 - Develop objective measures of biologic surrogates of pain & treatment response

Other Long-Term NIH Efforts

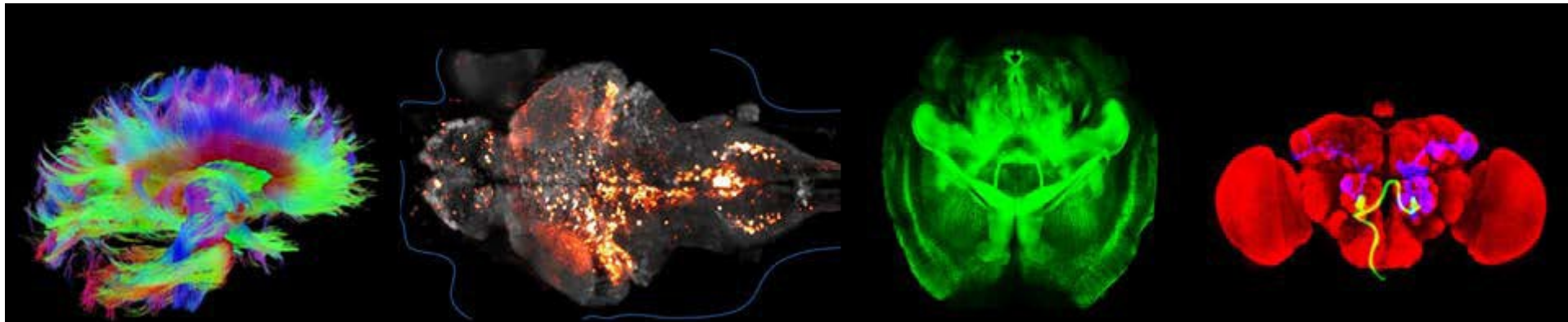
- Prevent the conversion of Acute to Chronic Pain.
 - Framework: Research initiative to define risk of conversion from acute to chronic pain.
 - Goal: Clinical trials of therapies that prevent the conversion rate, and
- Applying new technologies to discover novel pain targets
 - Framework: Research initiative to leverage emerging technology of BRAIN Initiative & other technologies on Rx development
 - Monitor and Modulate Pain Circuit Activity
 - Tools to measure, and quantitative analytical platforms to link behavior to circuitry activity
 - Goal: Discovery of new pain treatment targets and employ new neuro-technologies to improve pain Rx development

Brain Research through Advancing Innovative Neurotechnologies



- A focus on circuits, networks
- Measure fluctuating electrical, chemical patterns within circuits
- Understand how all of this
 - Helps generate our thoughts, actions
 - Improves diagnosis, treatment of disorders

www.braininitiative.nih.gov



BRAIN Expansion to Include Pain Research

BRAIN Initiative: Notice of Support for Research on the Fundamental Neurobiology of Pain Processing

Notice Number: NOT-NS-18-008

Key Dates

Release Date: September 12, 2017

Related Announcements

None

Issued by

National Institutes of Health (NIH)

National Eye Institute (NEI)

National Institute on Aging (NIA)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

National Institute on Deafness and Other Communication Disorders (NIDCD)

National Institute on Drug Abuse (NIDA)

National Institute of Mental Health (NIMH)

National Institute of Neurological Disorders and Stroke (NINDS)

National Center for Complementary and Integrative Health (NCCIH)

Purpose

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is aimed at revolutionizing neuroscience through development and application of innovative technologies to map neural circuits, monitor and modulate their activity, and understand how they contribute to thoughts, sensations, emotions and behavior. NIH has issued a variety of Funding Opportunity Announcements (FOAs) that will support projects that apply technologies to understand neural circuit function in the context of specific circuits, resulting in a diverse portfolio of research into the fundamental biology of nervous system function.

The purpose of this announcement is to notify the research community that NIH welcomes BRAIN Initiative applications targeting central nervous system nociceptive and pain circuits, as appropriate to the goals and requirements of specific BRAIN Initiative FOAs. Pain conditions represent an important public health problem and NIH continues to support research into pain pathologies through normal Institute and Center appropriations. However, pain and nociception are also components of normal nervous system function, and the BRAIN Initiative is committed to understanding pain circuits along with brain circuits underlying other sensory, motor, cognitive and emotional functions. It is expected that the unique opportunities of the BRAIN Initiative will enable production of detailed maps of pain circuits, and the adoption of powerful new tools for monitoring and modulating pain circuit activity, leading to significant advances in the understanding of pain and nociception.

For a list of past and open BRAIN Initiative FOAs, see <https://braininitiative.nih.gov/funding/>. For information on goals and requirements of specific BRAIN FOAs, contact Scientific/Program staff listed in the text of the respective announcements.

Inquiries

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Data Science at NIH

- As an initial step to strengthen the NIH approach to data, in 2014, the NIH Director created a unique position, the Associate Director for Data Science (ADDS), to lead NIH in advancing data science across the Agency. This resulted in the “Big Data to Knowledge” program (<https://commonfund.nih.gov/bd2k>) which includes the development of the Commons Pilot (<https://commonfund.nih.gov/bd2k/commons>)
 - This represents the first trans-NIH effort create a shared virtual space where scientists can work with the digital objects of biomedical research such as data and analytical tools
 - The NIH Data Commons Pilot will test ways to store, access, and share biomedical data and associated tools in the cloud so that they are findable, accessible, interoperable, and reusable (FAIR)
- NIH’s needs have evolved beyond the ADDS and the initial goals of Big Data to Knowledge (BD2K) program
 - NIH will next recruit for a new role – the NIH Chief Data Strategist

Data Science at NIH

- Key Responsibilities the NIH Chief Data Strategist:
 - Innovate a new data ecosystem to maximize the utilization and extraction of knowledge from the data generated by, and relevant to, NIH research, and will promote the coordination and harmonization of data use throughout the NIH, being sensitive to the unique programs and goals of the individual NIH Institutes and Centers.
 - Guide a new NIH Data and Technology Advancement Fellowship Program
 - Serve as Director of the Office of Data Science, DPCPSI
 - Will play a seminal role in implementing the vision summarized in the NIH's first Congressionally mandated NIH Strategic Plan for Data Science
 - In concert with NIH Scientific Data Council, establishing and managing NIH data-sharing policies
 - Coordinate data science activities with other government agencies, international funders, and private entities, as appropriate

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Government-Wide Effort

- *Relmage HHS* was launched in response to the White House Office of Management & Budget's directive to improve efficiency and effectiveness across the government
- Through *Relmage HHS*, the Department has drawn on insights from across HHS to identify opportunities to improve our ability to service the American people



Brief Background of Overall HHS Plan

Phase 1



Secretary's Guiding Principles:

- Engagement
- Empowerment
- Service
- Performance
- Stewardship
- Sustainability



GAO/OIG Recommendations:

- Analyzed and incorporated GAO/OIG recommendations



HHS Leaders' Ideation Summit:

- 2-week summit with 150+ HHS Staff and supporting Technical Writing Teams



Suggestions from all HHS Staff:

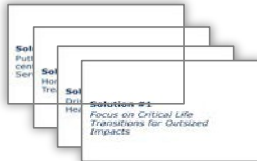
- Analyzed over 500 staff submissions to the HHS Suggestion Box & *ReImagine HHS* Email

Phase 2

1,966 initial ideas



28 initial solutions



Resulted in **Six Strategic Shifts**, used as organizing principles...

1. Putting People at the Center of HHS Programs
2. Leveraging the Power of Data
3. Generating Efficiencies through Streamlined Processes
4. Restoring Market Forces
5. HHS as a More Innovative and Responsive Organization
6. Moving to a 21st Century Workforce

...which informed initial **transformation proposals** aligned to these Shifts, grounded in analysis of HHS data, and incorporated into the Agency Reform Plan

We are here

Begin Building Implementation Plans



Relmage HHS Strategic Shifts

- 5. HHS as a More Innovative and Responsive Organization (Keagan Lenihan, SSE)
 - Align the Department's organizational functions with our overall mission and rectify any disconnects, as well as bring in the best from private sector's service delivery and operating model design experiences
 - Create Centers of Excellence and shared services for those functions that can be most effectively performed from the centralized location at the HHS Office of the Secretary
 - *Relmage HHS* at OpDiv level while ensuring increased collaboration and resource sharing within their own agency. NIH will be the pilot for this effort.

Optimize NIH

- As part of the “strategic shift” to make HHS a more innovative and responsive organization, NIH leadership across the agency has been considering how we can optimize our operations in support of the NIH research and training mission, while maintaining support of our highly valued workforce
- We are calling this initiative *Optimize NIH*

Optimize NIH Plan



Implications



*Sometimes a time consuming
process due to suboptimal
interconnectivity*



*Sometimes leads to
inefficiencies in cost*



*May allow for potential
duplications or inefficiencies
in staff and processes*

Key focus of the Administration: improve the efficiency, effectiveness,
and accountability

Proposed Reform

Initial focus will be Ethics, FOIA, and Committee Management with the goal of
creating Enterprise-wide service centers
Optimized functions through detailed process review driven by stakeholder team.

The Goals

- Increase efficiency and effectiveness of administrative functions within our agency
- Improve NIH operations, business processes, and coordination
- Maximize employee feedback in optimizing NIH operations, business processes, and coordination
- Initially optimize functions across Committee Management, Ethics, and FOIA

The Approach

- NIH will approach this optimization effort as we do all things – in a data-driven, scientific manner
- NIH stakeholders will perform a review to identify, map, and analyze all the key processes within the functions and identify opportunities for improvement.
 - After a detailed process review driven by stakeholder teams, OHR to conduct audit to define the staffing required with input from representatives in each functional area
 - Develop overall budget using accountability-based principles
 - Solicit independent validation of proposed plan
 - Implementation plan to optimize these functions in 2018



NIH...

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Turning Discovery Into Health

