



NIH Scientific Management Review Board



# Substance Use, Abuse, and Addiction Working Group Update

March 10, 2010

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**William Roper, MD, MPH**  
Dean of the School of Medicine and  
Vice Chancellor for Medical Affairs,  
University of North Carolina;  
CEO of the UNC Health Care System

# Overview

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- **SUAA Membership**
- **Context for Deliberations**
- **SUAA Working Group Charge**
- **Summary of Briefings to Date**
- **Deliberative Process**
- **Review of Data**
- **Next Steps**

# SUAA Working Group Membership

- **Non-Federal Members**

- **William Roper, MD, MPH (Chair)**

- Dean of the School of Medicine, Vice Chancellor for Medical Affairs, and CEO of the UNC Health Care System, University of North Carolina*

- **Deborah Powell, MD**

- Associate Vice President for New Models of Medical Education and Dean Emeritus, University of Minnesota Medical School*

- **Eugene Washington, MD, MSc**

- Dean of the David Geffen School of Medicine and Vice Chancellor of Health Sciences, University of California, Los Angeles*

- **Huda Zoghbi, MD**

- Professor and Howard Hughes Medical Institute Investigator, Baylor College of Medicine*

- **Norman Augustine (ad hoc)**

- Retired Chairman and CEO, Lockheed Martin Corporation*

# SUAA Working Group Membership *(cont.)*

- **Federal Members**

- **Josephine Briggs, MD**

*Director, National Center for Complementary and Alternative Medicine, NIH*

- **Richard Hodes, MD**

*Director, National Institute on Aging, NIH*

- **Griffin Rodgers, MD, MACP**

*Director, National Institute of Diabetes and Digestive and Kidney Diseases, NIH*

- **Lawrence Tabak, DDS, PhD**

*Director, National Institute of Dental and Craniofacial Research, NIH*

- **Francis Collins, MD, PhD *(nonvoting, ex officio)***

*Director, NIH*

# Context for Deliberations

- **Neuroscience research has revealed that addictive substances, including drugs and alcohol:**
  - **Differentially affect brain receptors and can result in unique neuropathologies**
  - **Similarly activate certain physiological pathways including the brain's reward circuit, which can result in compulsive substance use**
- **Considering both biological differences and similarities, does the current organization separating research institutes on drug and alcohol use, abuse, and addiction provide optimal infrastructure for supporting these areas of scientific research?**

# Context for Deliberations *(cont...)*

- **Social-Political:**
  - The NIH Reform Act established the SMRB to advise NIH on the use of organizational authorities
  - In 2003, the National Academies recommended considering merging NIAAA and NIDA (option of a combined institute of addiction also identified by the Lewin Group in 1988)
  - The Drug Abuse Education, Prevention, and Treatment Act of 2001 (S.304) required the DHHS Secretary to request an IOM study to determine whether combining NIDA and NIAAA would strengthen scientific research efforts and increase economic efficiency (*study has yet to be conducted*)

# SUAA Working Group Charge

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**—..to recommend whether organizational change within NIH could further optimize research into substance use, abuse, and addiction and maximize human health and/or patient well being.”**

# Briefings to Date

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# Briefings to Date

- Introduction to SUAA research at the NIH from current Institute Directors



**Dr. Kenneth Warren**  
*Acting Director, NIAAA*



**Dr. Nora Volkow**  
*Director, NIDA*

## Briefings to Date *(cont.)*

- **Perspectives from prevention specialists, treatment providers, patient advocates, and policy specialists**
  - **Ms. Nancy Freudenthal**, *First Lady of Wyoming*
  - **Dr. Sheppard Kellam**, *Johns Hopkins Bloomberg School of Public Health*
  - **Dr. Herbert Kleber**, *Columbia University College of Physicians and Surgeons and NY State Psychiatric Institute*
  - **Dr. Marc Schuckit**, *University of California and the VA San Diego Healthcare System*
  - **Mr. Tom Donaldson**, *National Organization on Fetal Alcohol Syndrome*
  - **Ms. Sue Rusche**, *National Families in Action and Parent Corps*
  - **Dr. John Carnevale**, *Carnevale Associates, LLC*

# Briefings to Date *(cont.)*

- **Perspectives on the science of SUAA research**
  - **Dr. Huda Akil**, *University of Michigan*
  - **Dr. Adron Harris**, *University of Texas at Austin*
  - **Dr. Michael Charness**, *Harvard Medical School and Boston University School of Medicine*
  - **Dr. Mary Jeanne Kreek**, *Rockefeller University Hospital*
  - **Dr. Mark Goldman**, *University of South Florida*
  - **Dr. Linda Porrino**, *Wake Forest University School of Medicine and College on Problems of Drug Dependence*

# Briefings to Date *(cont.)*

- **Perspectives on the science of SUAA research** *(cont.)*
  - **Dr. Thomas Kosten**, *Baylor College of Medicine*
  - **Dr. Stephanie O'Malley**, *Yale University School of Medicine and Connecticut Mental Health Center*
  - **Dr. Scott Friedman**, *Mount Sinai School of Medicine*
  - **Dr. David Vlahov**, *New York Academy of Medicine, Columbia University, and Johns Hopkins Bloomberg School of Public Health*
  - **Dr. Thomas Greenfield**, *Public Health Institute and University of California*
  - **Dr. David Rosenbloom**, *Columbia University*

## Briefings to Date *(cont.)*

- **Alternative models for organizing SUAA research: Perspectives from the judicial system, academia, and industry**
  - **Ms. Linda Chezem, *Purdue University***
  - **Ms. Pamel Rodriguez, *Treatment Alternatives for Safe Communities***
  - **Dr. Steven Hyman, *Harvard Medical School***
  - **Dr. John Krystal, *Yale University, U.S. Department of Veterans Affairs***
  - **Dr. Bankole Johnson, *University of Virginia***
  - **Dr. Steven Paul, *Eli Lilly and Company***

## Briefings to Date *(cont.)*

- **Perspectives from former NIAAA and NIDA Directors:**
  - Dr. Enoch Gordis, *Former Director of NIAAA (1986 – 2001)*
  - Dr. Alan Leshner, *Former Director of NIDA (1994 – 2001)*
  - Dr. Ting-Kai Li, *Former Director of NIAAA (2002 – 2008)*
- **Perspectives from the NIAAA and NIDA Advisory Councils**

## Briefings to Date *(cont.)*

- **Briefed the NIH Director, SMRB Chair, and Chair of SMRB Working Group on the NIH Intramural Research Program on SUAA Working Group status**
  - **Francis Collins, M.D., Ph.D.,** *Director of NIH*
  - **Norman Augustine,** *Retired Chairman and CEO of Lockheed Martin Corporation, Chair of SMRB*
  - **Arthur Rubenstein, M.B.B.Ch.,** *Executive Vice President of the University of Pennsylvania for Health System and Dean of the University of Pennsylvania School of Medicine, Chair of SMRB IRP Working Group*

# **Summary of Findings from Briefings to Date**

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# Advocates FOR Reorganization

- **Science would benefit from synergy of commonalities:**
  - **Emerging scientific research indicates similar reward pathways underlie compulsive behavior**
  - **Alcohol and drug abuse often begins in adolescence with similar early risk factors**
- **High prevalence of drug users also use alcohol, suggesting both scientific and policy justification**
- **Segregation of disciplines creates public health gaps**

# Advocates FOR Reorganization *(cont...)*

- **Reorganization, particularly merging, would:**
  - **Create synergy for advancing the science of substance use, abuse and addiction**
  - **Increase flexibility in cross-training**

# Advocates **AGAINST** Reorganization

- **Reorganization would create research gaps in understanding:**
  - **Ubiquitous effects of alcohol**
  - **Unique factors underlying abuse and addiction**
- **Contextual and socio-cultural differences warrant separate, focused research efforts**
- **Lack of compelling evidence to suggest reorganization would improve treatment, prevention, research, and/or training**
- **Current organization mirrors the separation of professional and scientific associations**

# Advocates **AGAINST** Reorganization *(cont...)*

- **Reorganization, particularly merging, would:**
  - **Decrease emphasis on effects of alcohol on multiple organ targets**
  - **Jeopardize priority/budget of alcohol-related research**
  - **Create organizational/administrative obstacles and reversals**

# Questions Raised

- **Are other areas of research being examined for potential inclusion in a merged Institute?**
- **Has the SMRB considered broadening the mission/scope of a merged Institute?**
- **Has the SMRB investigated intra-governmental relationships (e.g., ONDCP oversight of NIDA budget)?**
- **Has industry participated in the discussion and/or voiced an opinion?**
- **Patients have no difficulty combining substances, why does the government?**
- **Will the SMRB recommend a single solution or multiple solutions?**

# Issues the Board should Consider

- **Both Institutes are already underfunded despite the burden of illness; Potential funding loss due to stigma associated with combining these areas of research**
- **The public health message for alcohol is different: moderate alcohol usage may be healthy; immoderate usage is not**
- **Focusing on reward pathways creates a dogma about abuse and addiction; constrains science to only one potential mechanism**
- **NIDDK or NIA are more logical partners for NIAAA than NIDA**
- **If a merger is recommended, there needs to be a —genuine” merge of the Institutes and not the creation of two departments within one IC**

# NIAAA Advisory Council Position

- **Resolution of Council passed on February 3, 2010: 14 in favor; 0 opposed; 1 abstention**
- **—The NIAAA Council strongly advises against an NIH reorganization that eliminates NIAAA as an independent Institute. We encourage increased collaboration across NIH Institutes and Centers to strengthen research on the use, abuse, and addiction to alcohol, tobacco, drugs of abuse, and high-fat and high-sugar foods. We also advocate increased collaboration to improve the diagnosis and treatment of the co-morbid mental health disorders associated with addiction.”**

# NIDA Advisory Council Position

- Resolution of Council passed on March 1, 2010: 15 in favor; 0 opposed
- **—We resolve that the benefits derived through combining the research efforts for all drug use and addiction into a single entity outweigh the benefits in continuing the status quo. Therefore, the National Advisory Council of the National Institute on Drug Abuse advises that the Secretary of Health and Human Services and Director of NIDA vigorously should support efforts to combine and focus within a single NIH Institute research on the causes, mechanisms, prevention, and treatment of the non-medical use of, and addiction to, all addictive drugs.”**



# Deliberative Process Step 1: Assessing the Need for Change

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*Step 1.*  
Assess the Need for Change

Is SUAA research at NIH capitalizing on scientific opportunities and/or meeting public health needs?

Could reorganization better optimize SUAA research at NIH?

# Steps and Considerations: STEP 1

- ***Immediate Crisis***
  - Are there significant organizational impediments preventing effective responses to external forces?
- ***Unaddressed Scientific Opportunities***
  - Is there a health problem or an important area of scientific inquiry not addressed because of the limitations imposed by the current organization?
- ***Changes in Scientific Landscape***
  - Have there been scientific discoveries that create new opportunities for innovation and advance that would benefit from reorganizing components of the NIH?
- ***Evolving Emergent Public Health Needs***
  - Are there evolving public health needs on the horizon that will create new challenges and opportunities that would be best faced by reorganizing components within NIH?
- ***Need for Improvements in Quality and/or Efficiency of Research***
  - Is there a problem (or could things be more effective) in the supply and demand of human and/or physical resources (e.g., training, dissemination of research/public health messages)?

# Steps and Considerations: STEP 1 *(cont.)*

- In assessing the need for organizational change to optimize SUAA research at NIH, the working group has requested the following data:
  - Major challenges facing the advancement of SUAA research
  - Funding history and Institute success rates
  - Institute support for early career investigators
  - Extent of SUAA research in the entire NIH research portfolio
  - SUAA demographics

# Data Requested

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# Research/Public Health Needs Not Currently Addressed – NIAAA Perspectives

- **A compendium of the pharmacokinetic and pharmacodynamic interactions between alcohol and the therapeutics used to treat general medical and psychiatric conditions (e.g., hypertension, diabetes, epilepsy, depression, etc.)**
- **Research on the generation of novel metabolites resulting from the in situ interaction of alcohol with opiates, stimulants, hallucinogens, or inhalants (e.g., the production of coco-ethylene) and their pharmacokinetic and pharmacodynamic properties and toxicity**
- **Mechanisms by which alcohol increases risk for certain cancers**
- **Encouraging the hesitant patient to seek treatment**

# Research/Public Health Needs Not Currently Addressed – NIDA Perspectives

- **Lack of pharmaceutical industry interest in developing medications to treat addiction/alcoholism**
- **Insufficient involvement of the medical community in preventing and treating drug addiction and alcoholism**
- **Although treatments for substance abuse are available, they are not being widely used by those who need them**
- **There is a bottleneck in translating treatments for substance abuse from bench to bedside to the community**

# Funding History and Success Rates - Findings

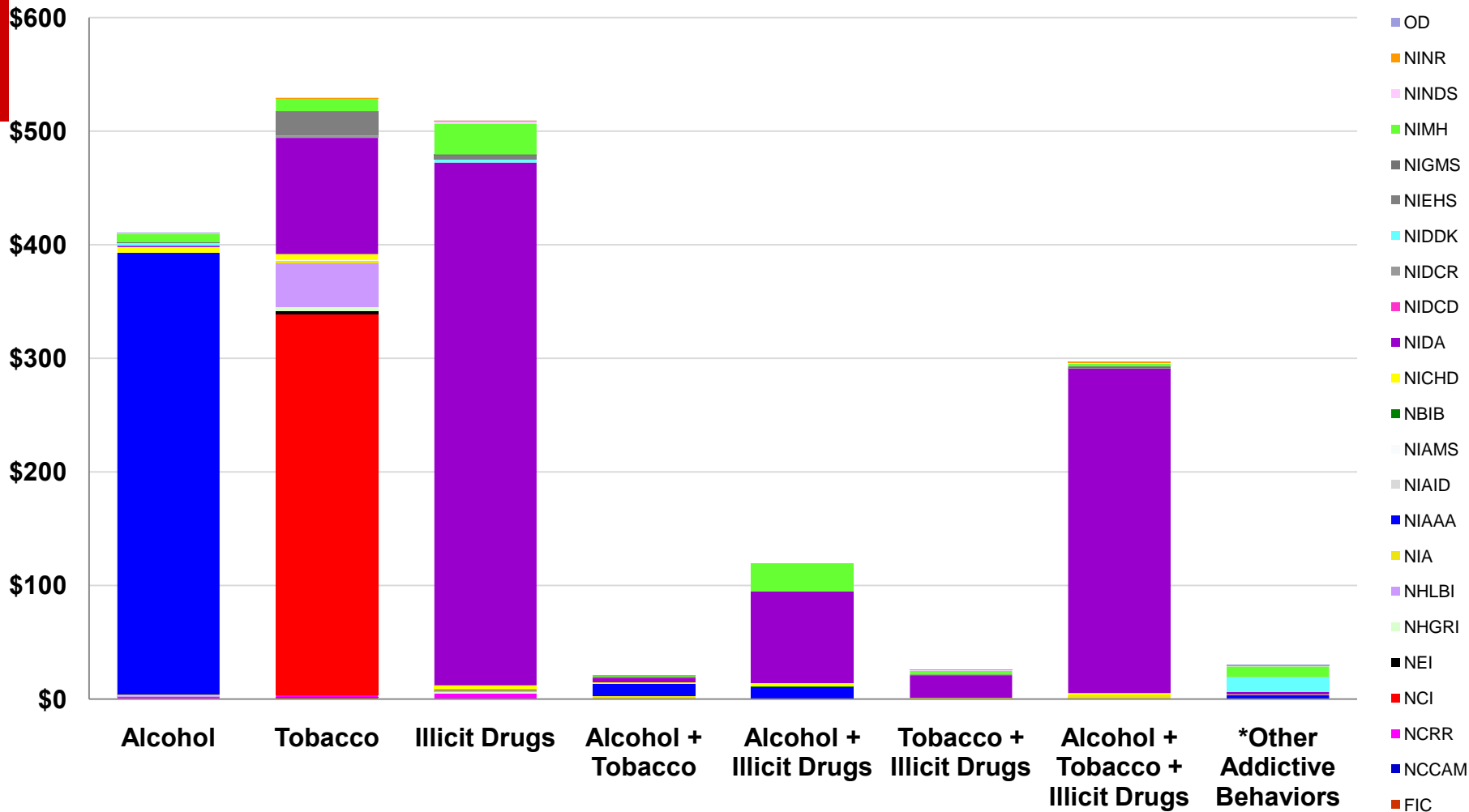
- **Similar rates of budget growth**
  - NIAAA = 69% increase from 1999 appropriation
  - NIDA = 67% increase from 1999 appropriation
- **Currently similar grant success rates, although different trends since 1999**
- **Different rates of growth in number of research project grants reviewed**
  - NIAAA = 23% increase since 1999
  - NIDA = 81% increase since 1999

# Support for Early Stage Investigators - Findings

- **Training support (FY09)**
  - Pre-doctoral awards: NIAAA = 164; NIDA = 289
  - Post-doctoral awards: NIAAA = 131; NIDA = 244
- **K Awards (FY09)**
  - NIAAA = 97 (21% increase from 2003)
  - NIDA = 251 (9% increase from 2003)



# Funding for SUAA Research Across NIH



\* Data estimates were provided by individual ICs and do not reflect official NIH budget numbers.

# Demographics of SUAA - Findings

- **Age groups with highest percent use within the last month:**
  - Alcohol: 21 and older
  - Illicit drugs: 16-29
  - Cigarettes: 18 and older
- **Number of 12 yr olds and older reporting substance abuse or dependence in the last year (rates of abuse have not changed 2002 - 2008)**
  - Alcohol: ~15 million
  - Illicit Drugs: ~4 million
  - Both Alcohol and illicit drugs: ~3 million

# Demographics of SUAA - Findings *(cont.)*

- **Percent of individuals aged 12-17 reporting substance abuse or dependence in the last year**
  - ONLY Alcohol: 5.9% in 2002; 4.9% in 2008
  - ONLY illicit drugs: 5.6% in 2002; 4.6% in 2008
  - EITHER alcohol or illicit drugs: 8.9% in 2002; 7.6% in 2008
- **Substance Abuse and Mental Health**
  - 2.5 million adults have both a substance use disorder and a serious mental illness

# Demographics of SUAA - Findings *(cont.)*

- **Substance Abuse and Mental Health *(cont.)***
  - **Percent of adults reporting a major depressive episode in the past year who were dependent upon:**
    - Either drugs or alcohol: 20%
    - Drugs only: 8%
    - Alcohol only: 16%
  - **Percent of 12-17 year olds reporting a major depressive episode in the past year who used:**
    - Illicit drugs: 37%
    - Cigarettes: 4%
    - Alcohol: 3%

# Preliminary Findings

- **Working Group has thoroughly discussed and debated the issue, based on perspectives heard and data collected**
  - **Agreement that the status quo is not ideal for fulfilling NIH mission and optimizing research into substance use, abuse and addiction**
  - **Eager to improve how NIH manages research into substance use, abuse and addiction**

# Deliberative Process Step 2: Considering the Spectrum of Options

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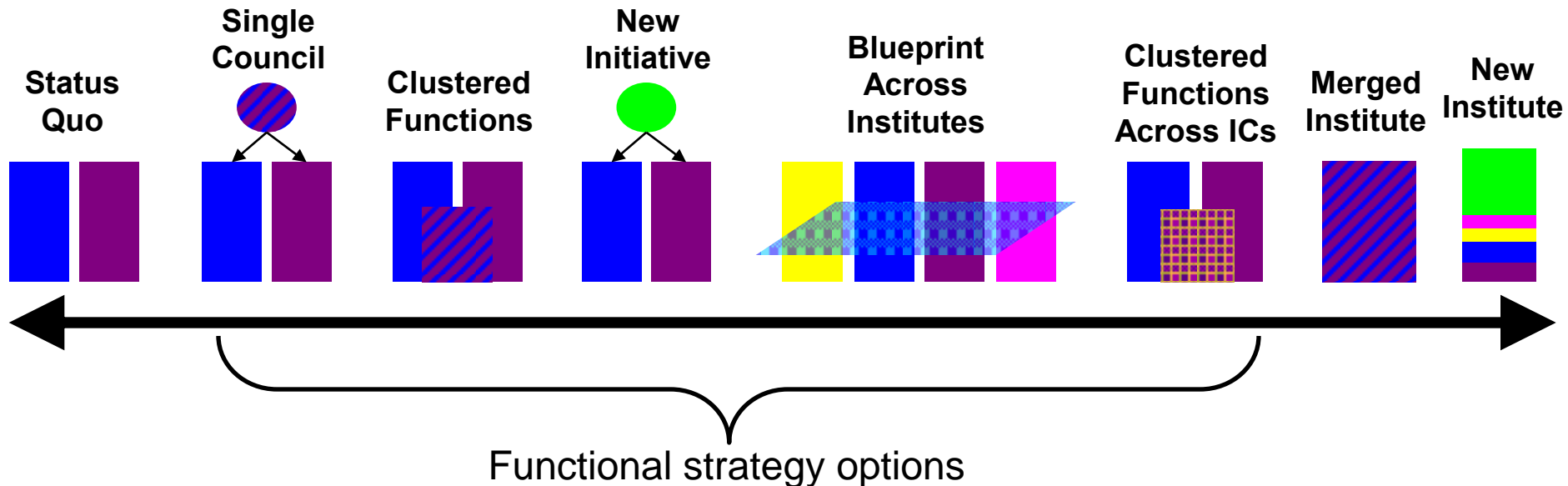
**Step 2.**  
**Evaluate Options for Change**

**What are the options  
for organizational  
change?**

**Which one is best for  
addressing the need  
for change?**

# Full Spectrum of Options

- Each option needs to be carefully considered to maximize integration
- Each option is a possible element of final recommendation—various strategies are not mutually exclusive and a combination can be identified to best address the need



# Preliminary Findings

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- To date, the working Group disagrees as to best way to proceed: structural vs. functional integration



# Preliminary Findings *(cont.)*

- **Minority View:**
  - **A structural reorganization is needed, involving a merger of NIDA and NIAAA into a single institute focused on alcohol and drug abuse and addiction**
    - **The change in scientific landscape, research opportunities, public health needs, and the potential for more efficient research provide the rationale for considering structural change**
    - **Substantial vision of a new way of approaching the science and addressing public health needs ought to compel us to take the difficult step towards merging the two**

# Preliminary Findings *(cont.)*

- **Majority View:**
  - **Best way to proceed is a functional reorganization of all research programs with a relevant scientific focus**
    - **The change in scientific landscape, research opportunities, public health needs, and the potential for more efficient research provide the rationale for considering change, but the majority are not yet convinced structural changes would benefit the science in a way that functional integration could not**
    - **See substantial room to improve the science through functional integration across the entire NIH**
    - **Evidence that functional strategies have worked in the past, in other scientific areas, with varying degrees of success**

# Next Steps

- **Having agreed that there is a need for organizational change, Working Group will:**
  - **Fully analyze potential structural and functional options, including historic success of different models**
  - **Fully analyze pros and cons of each option**
- **Present working group recommendation at next SMRB meeting**

# Anticipated Timetable

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- **April: Draft recommendations proposed to full Board via public teleconference**
- **May 17-19: Stakeholder meetings held during full Board meeting in Bethesda**
- **May-June: Integrate feedback from stakeholder meetings into recommendations**
- **June-July: Full Board teleconference vote via public teleconference**