SCIENTIFIC MANAGEMENT REVIEW BOARD

REPORT ON SUBSTANCE USE, ABUSE, AND ADDICTION RESEARCH AT NIH

NOVEMBER, 2010

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EXECUTIVE SUMMARY

The Scientific Management Review Board (SMRB) was established under the National Institutes of Health (NIH) Reform Act of 2006 to advise the NIH Director and other appropriate officials on the use of certain organizational authorities reaffirmed under the same act. At the inaugural SMRB meeting on April 27-28, 2009, Board members unanimously agreed to convene the Substance Use, Abuse, and Addiction (SUAA) Working Group. This decision was based, in part, on prior recommendations to conduct a thorough analysis of the organizational structure of SUAA research at NIH and evaluate a potential merger of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA). The SUAA Working Group was asked to recommend to the full SMRB whether organizational change could optimize SUAA research at NIH, ultimately improving the health and well-being of individuals affected by this problem.

The Working Group members agreed that discussions about a potential reorganization of SUAA research should be driven by science and public health considerations and not by concerns about the management of NIH; the SMRB subsequently endorsed this view. In formulating its recommendations, the SUAA Working Group considered scientific opportunities, public health needs, and new research technologies; SUAA research under the existing NIH structure; and criteria for contemplating, strategies for implementing, and metrics and methodologies for evaluating changes in the organization and management of NIH. Experts and stakeholders were solicited for input on SUAA research at NIH, public health needs in SUAA research, the science of SUAA research, and options for organizational change in SUAA research at NIH.

Following the process for contemplating organizational change at NIH described in *Deliberating Organizational Change and Effectiveness,* a report of the SMRB, the SUAA Working Group unanimously agreed that the status quo is not ideal for fulfilling the NIH mission and optimizing SUAA research. After determining that organizational change is needed, the Working Group considered a variety of functional strategies and structural reorganization options. The Working Group recommended to the full Board that the scope of reorganization should be focused on addiction-related research and not restricted to drug and alcohol research.

The Working Group recommended two options for reorganizing SUAA research at the NIH: (1) a single institute focused on addiction, to which all NIH addiction-related research would be relocated, or (2) a trans-NIH addiction program with

participation from all institutes and centers that fund addiction-related research. The Working Group also emphasized that, in accordance with the framework enunciated in *Deliberating Organizational Change and Effectiveness* report, the success of either option depends upon the development and execution of a plan for rigorous, systematic evaluation based upon clear, sound metrics.

At its meeting on September 15, 2010, the SMRB considered the final recommendations of SUAA Working Group. The SMRB concurred with the Working Group's finding that the current organization of SUAA research at NIH is not optimal Members unanimously agreed that some form of reorganization is required in order to effectively capitalize upon existing and potential synergies, address scientific opportunities, meet public-health needs, and train the next generation of investigators. The SMRB also endorsed the conclusion that such a reorganization should encompass all addiction-related research within the NIH and not just the programs of NIDA and NIAAA.

Presented with the two options for organizational change identified by the SUAA Working Group, a majority of the Board (12 favored; 3 opposed; 1 abstained) voted to recommend to the NIH director the establishment of a new institute for substance use, abuse, and addiction-related research and the dissolution of NIAAA and NIDA. In the view of this majority, this option has the greater potential to improve and advance SUAA research at NIH.

I. INTRODUCTION

The National Institutes of Health (NIH) Reform Act of 2006 (Public Law 109-482) reaffirmed certain organizational authorities of agency officials to: (1) establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH, including adding, removing or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The Reform Act also established the Scientific Management Review Board (hereinafter, SMRB or Board) to advise the NIH Director and other appropriate agency officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

This report distills the deliberations of the SMRB and of its Substance Use, Abuse, and Addiction (SUAA) Working Group and provides conclusions and recommendations in response to the question of whether organizational change within NIH could further optimize research into substance use, abuse, and addiction and thereby improve the health and well-being of individuals affected by this significant problem in public health.

A. Impetus for and Charge to the SUAA Working Group

Over the past several decades, groups and individuals have questioned whether the current organization at NIH, with separate research institutes focused on drugs and alcohol use, abuse, and addiction, provides the optimal infrastructure for supporting these areas of scientific research.[1] In 2003, an expert panel convened by the National Academies advocated undertaking a study to evaluate a potential merger of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA). This panel also recommended that the proposed study be subjected to a formal process of public scrutiny and consideration.

In light of this question and prior recommendations, at the inaugural SMRB meeting on April 27-28, 2009, Board members unanimously agreed to convene the SUAA Working Group. The SUAA Working Group was asked to recommend to the full SMRB whether organizational change within NIH could further optimize research into substance use, abuse, and addiction and maximize human health and/or patient well-being.

[1] Lewin and Associates, (1988). *Examination of the Advisability and Feasibility of Restructuring Federal Alcoholism, Drug Abuse and Mental Health Activities.* Washington, D.C.; National Academy of Science. (2003). *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges.* Washington, D.C.: National Academies Press.

B. SUAA Working Group Process

In addressing its charge, the SUAA Working Group included the following in its considerations:

- Scientific opportunities, public health needs, and new research technologies;
- Research in these areas under the existing NIH structure;
- Criteria for contemplating changes in the organization and management of NIH;
- Strategies for implementing changes in the organization and management of NIH; and
- Metrics and methodologies that could be used for evaluating the impact of changes in the organization and management of NIH.

The SUAA Working Group met 12 times by teleconference and three times in person and hosted two public forums (September 23, 2009 and May 18, 2010) to solicit input from experts and stakeholders. Briefings were provided on the following topics (see Appendix A for a list of individual speakers and dates):

- SUAA research at NIH, with overviews from current NIAAA and NIDA directors;
- Public health needs in SUAA research, with perspectives from prevention specialists, treatment providers, patient advocates, and policy specialists;
- The science of SUAA research, with perspectives from distinguished scientists;
- Alternative models for organizing SUAA research, with perspectives from members of the judicial system, academia, and industry;
- The potential reorganization of SUAA research, with perspectives from former NIAAA and NIDA directors; and
- Options for organizational change, with perspectives from members of the community, treatment and prevention specialists, early-stage investigators, and current NIH grant holders.

On February 3, 2010, the Chair of the SUAA Working Group briefed the advisory councils of NIAAA and NIDA on the reorganization options under consideration by the SUAA Working Group and received input from members of both advisory councils. On February 22, 2010, the chair of the SUAA Working Group briefed the NIH director, the chair of the SMRB, and the chair of the Intramural Research

Program Working Group on the status of its deliberations. The SUAA Working Group also provided continual updates to and solicited input from the entire SMRB during its public deliberations held on November 13, 2009, March 10, 2010, and May 18–19, 2010. The full Board voted on recommendations regarding this issue on September 15, 2010.

II. HISTORY OF SUBSTANCE USE, ABUSE, AND ADDICTION RESEARCH AT NIH: ORIGINS OF NIAAA AND NIDA

A. Organizational History

During the early 1970s, pressure to address the needs of persons suffering from substance-use disorders resulted in the passage of several legislative provisions, which ultimately led to the establishment of the precursors to the current NIAAA and NIDA. The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 mandated the establishment of NIAAA as a separate entity within the National Institute of Mental Health (NIMH). Concurrently, heightened concern regarding illicit drug abuse resulted in a rapid expansion of drug-abuse programs supported by NIMH. The Drug Abuse and Treatment Act of 1972 subsequently mandated the establishment of NIDA, also to be housed within NIMH.

In 1973, the Assistant Secretary for Health established a task force, in part, to determine how to address the needs for research, services, and training in the alcoholism, drug abuse, and mental illnesses fields. Through the course of its deliberations, the group concluded that the fields of drug abuse and alcohol abuse should be combined steadily because: (1) basic research and training needs were thought to be similar and (2) there were increasing numbers of people who abused both drugs and alcohol. The task force report also noted differences between the substance abuse and "mental health fields," despite their close historical association in research and practice.[2]

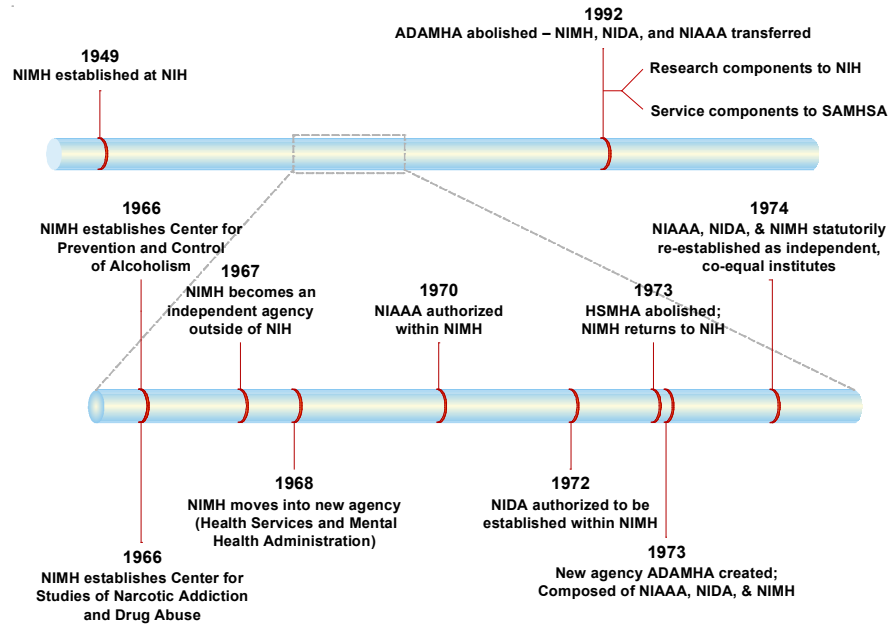
In 1973, the Secretary of the Department of Health, Education, and Welfare (now the Department of Health and Human Services) removed NIAAA, NIDA, and NIMH from NIH and established them as autonomous institutes under the newly created Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). This reorganization elevated NIAAA and NIDA to equal status with NIMH, and each institute's mission included research, training, and services. This reorganization

[2] E. A. Gardner, (1973) *Final Report of the Mental Health Task Force.* Washington D.C.: Department of Health and Human Services.

became a matter of controversy in 1987, when some scientists and the National Alliance for the Mentally Ill (NAMI) expressed the view that research funding was lagging as a result of NIMH's placement within ADAMHA, which housed both services and research programs. These groups advocated legislation mandating the return of NIMH to NIH. NAMI also favored the transfer of NIDA and NIAAA to NIH, although this was not included in the proposed legislation.

The debate over the optimal organization of basic research and health services programs continued, with renewed concerns regarding the merits of having these components housed together.[3] In 1987, the Senate requested a position statement from the Department of Health and Human Services (HHS), which in turn commissioned Lewin and Associates to investigate the organizational options for ADAMHA and the organizational preferences of interested parties. Ultimately, ADAMHA was dissolved in 1992, and the research components of NIMH, NIDA, and NIAAA were transferred back to NIH as independent research institutes. The services components of ADAMHA became the Substance Abuse and Mental Health Services Administration (SAMHSA).

Figure 1. Organizational history for NIAAA and NIDA.



[3] Institute of Medicine (1991), *Research and Service Programs in the PHS: Challenges in Organization.* Washington, D.C.: National Academies Press.

B. Previous Assessments and Recommendations

As the organizational history of these institutes shows, the optimal organization of SUAA research has been a topic of recurring debate for several decades. In 1988, Lewin and Associates recommended considering the creation of a combined institute on addiction.[4] Several years later, the Drug Abuse Education, Prevention, and Treatment Act of 2001 required the HHS secretary to request an Institute of Medicine study to determine whether combining NIDA and NIAAA would strengthen scientific research efforts and increase economic efficiency; however, this study has yet to be conducted.

In 2003, in response to a congressional request to review the organizational structure of NIH, the National Academies recommended that NIH undertake a study to determine whether NIAAA and NIDA should be merged.[5] The National Academies report asserted that the arguments for combining the two institutes "stem from overlap in their missions and substantive foci." The report also noted public statements made by the directors of both institutes about the strong association between the use of tobacco and illicit drugs and the abuse of alcohol. The report also noted that:

> "…addiction, prevention and treatment approaches that are fundamentally similar for abuse of alcohol and other substances make it desirable from a public health perspective to address all substances of abuse when opportunities arise… Arguments against merger appear to be primarily nonscientific; for example, the alcohol industry might strongly and successfully oppose such a merger to avoid being associated, even indirectly, with considerations of illegal drugs. In the Committee's view, substantive arguments against merger are not convincing. One suggests that alcohol requires a separate institute because it is unique in affecting every cell in the body; but other abused drugs studied by NIDA, such as inhalants, also affect all cells. Another argument is that alcohol is unique among abused substances in being legal, at least for adults, and thus everything surrounding the drug is unique. On the other hand, NIDA supports a large amount of research on nicotine addiction, and smoking is also legal for adults. A merger of NIAAA and NIDA would seem to offer many advantages, scientifically and with respect to improved health, and should be studied carefully. The broader scientific relationships and physical location of these two institutes with other neurosciences institutes (especially NIMH and the National Institute of Neurological Diseases and Stroke) should also be considered."

[4] Lewin and Associates, op. cit
[5] NAS, op. cit., pp 72-73.

The SMRB's decision to undertake the current review was motivated, in part, by these prior recommendations urging a thorough analysis of the optimal organizational structure for SUAA research at NIH. The establishment of the SMRB to advise NIH on the use of organizational authorities has provided a timely and appropriate venue for addressing this issue.

It should be noted that the subject of merging institutes and centers has been questioned in relation to the broader goal of streamlining the organizational structure of NIH. There are now 27 institutes and centers at NIH, and governance of such a large and complex organization has become difficult. The SUAA Working Group members agreed, however, that discussions about a potential reorganization of NIAAA and NIDA should be driven by science and public health considerations and not by concerns about the management of NIH as a whole. This principle of deliberation was subsequently endorsed by the full SMRB.

III. SUAA WORKING GROUP FINDINGS

The SUAA Working Group heard from a broad range of stakeholders, including representatives from both the alcohol and drug use, abuse, and addiction research and treatment communities, some of whom advocated reorganization and some who objected to it. The Working Group and the entire Board appreciated the time, effort, and passion of those who made presentations to the SMRB, participated in SUAA panel discussions, made statements during public forums, and submitted written comments (all received comments can be found at http://smrb.od.nih.gov/meetings/).

A. The Evolving Landscape of Science and Public Health

Acknowledging the critical role of NIH in supporting biomedical and behavioral research on substance use, abuse, and addiction, the Working Group carefully surveyed the scientific and public health landscape with an eye toward scientific opportunities and unmet public health needs. The following themes that emerged during the deliberations are detailed below.

i. Advances in Neuroscience

Research in neuroscience has revealed that many substances with the potential for abuse may have similar effects on the brain. For example, while alcohol and cocaine activate different receptors and have unique physiological and behavioral effects, research suggests that the compulsion toward addiction often shares a common pathway.

According to testimony provided by experts in SUAA research, unique genetic sites have been associated with risk for specific disorders related to alcohol and several drugs of abuse. With regard to the rewarding properties of addiction, although different drugs activate different receptors in the brain, they all either directly or indirectly elevate dopamine levels in the limbic system, which acts as the brain's endogenous reward system. Stimulation of this circuitry produces feelings of euphoria, motivates behaviors necessary for survival, and can result in a learned association between substance use and pleasure, which is believed to underpin compulsive behaviors and addiction. Thus, understanding addiction as a usurpation of normal reward-related learning suggests that prevention and treatment strategies may be transferable across addictions.

Moreover, there is substantial evidence that addiction is a developmental disease. The roots of abuse and addiction across multiple substances take hold in adolescence and the teen years, suggesting commonalities in the initial developmental pathways and key windows of opportunity for prevention and intervention.

ii. Co-morbidity

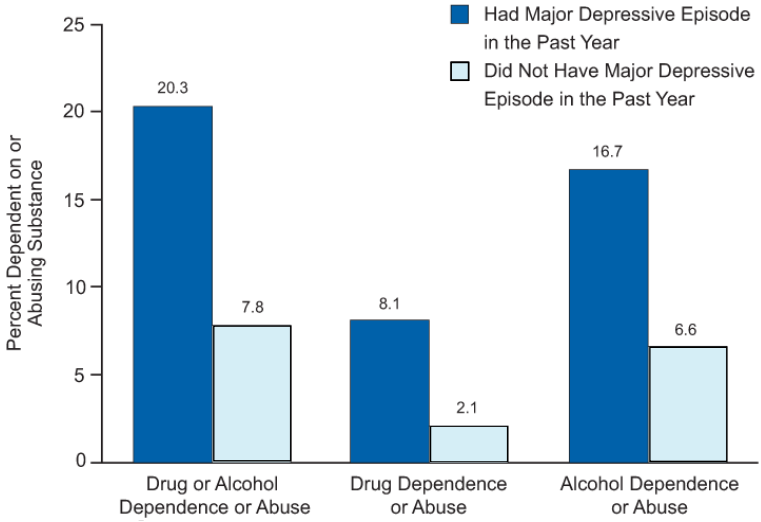
Many substance abusers suffer from multiple drug dependencies and/or co-morbid conditions. Some data suggest that treating one disorder without concurrently treating the other can lead to higher relapse rates for either substance. In addition, common pathways across multiple forms of compulsive behaviors offer unique opportunities for developing potential therapeutic strategies. For example, cannabinoids and alcohol activate similar reward pathways, and cannabinoid 1 receptors may regulate the reinforcing effects of alcohol and mediate alcohol relapse.[6] There also are commonalities among psychological and behavioral interventions for substance abuse, including cognitive behavioral therapy, contingency contracting, and motivational enhancement therapy.

Imperative to this discussion is the complex relationship between substance abuse and mental-health disorders. Data indicate that as of 2008, 2.5 million adults suffered from both a substance-use disorder and a serious mental illness.[7] Data also indicate a link between major depression and substance abuse and suggest that there is a unique relationship between the two across development. For example, 16 percent of adults reporting a major depressive episode in the past year abused or were dependent upon alcohol, while only 8 percent abused or were dependent upon drugs (not specified as licit or illicit; Figure 2). Regarding adolescent use, 37 percent of 12- to 17-year-olds suffering from a major depressive disorder in the

[6] Herbert Kleber, October 23, 2009 presentation to the Working Group.

[7] Substance Abuse and Mental Health Services Administration. (2009). R*esults from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, Md.

Figure 2. Substance dependence or abuse among adults aged 18 or older, by major depressive episode in the past year, 2008.



SOURCE: Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, Md.

last year reported using illicit drugs.[8] The intersection of mental-health status and substance use provides an additional opportunity for advancing research with the end goal of improving public health.

B. Unaddressed Scientific Opportunities and Public Health Needs

Both NIAAA and NIDA provided lists of scientific opportunities and public health needs in SUAA research that neither institute addresses sufficiently. Their responses are as follows:

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.);

[8] Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

- 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; and
- Encouragement of patients who are hesitant to seek treatment.

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;
- Relatively low rates of treatment by individuals with substance abuse, despite available treatments; and
- A bottleneck in translating treatments for substance abuse from bench to bedside to the community.

Through careful analyses of the incidence and prevalence of various forms of substance use, abuse, and addiction,[9] the Working Group identified adolescent and young-adult substance use as an area of research that warrants further attention. A noteworthy finding is that the age of first use of alcohol is correlated with future abuse and/or dependence. A similar correlation exists for illicit drugs, as those who first used marijuana by the age of 14 were more likely to abuse or be dependent upon illicit drugs than those who first tried marijuana at 19 (13.5 percent vs. 2.2 percent of adults). Moreover, in 2008, the highest prevalence of substance dependence or abuse occurred among young adults, ages 18-25 (20.8 percent), followed by youth who are 12-17 years old (7.6 percent), followed by adults who are 26 and older (7.0 percent). These data suggest an urgent need to target effective prevention, intervention, and treatment strategies towards these populations.

C. Stakeholder Perspectives on Structural Reorganization of NIDA and NIAAA

In the course of their deliberations, the SUAA Working Group and the SMRB as a whole encountered diametrically opposed opinions regarding the potential reorganization of SUAA research at NIH. Even the respective scientific advisory

[9] Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

councils of both NIAAA and NIDA were opposed in their recommendations on the best course of action with respect to organizational change. On February 4, 2010, the NIAAA Advisory Council passed a resolution (14 favored; 0 opposed; 1 abstained) strongly advising NIH against a reorganization that eliminates NIAAA as an independent institute. The resolution encouraged "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." (See Appendix B for full resolution.) On March 1, 2010, the NIDA Advisory Council unanimously passed a resolution (15 favored; 0 opposed) supporting the creation of a single entity for all drug use and addiction research and recommended that the Secretary of DHHS and the NIDA Director "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." (See Appendix C for full resolution.)

These resolutions generally reflect the views of respective NIAAA and NIDA staff, grantees, and constituency groups. In summary, both the alcohol and drug research communities largely favor increased collaboration between the two institutes. However, the drug research community believes that increased collaboration would be achieved best through a structural merger of the two institutes. The alcohol research community believes that these objectives could be achieved without a structural merger and cautions that this type of reorganization might jeopardize advances in alcohol research. A summary of each perspective is provided in the following subsections. In part, because of the context within which these deliberations occurred, a great deal of the discussions focused on the disposition of NIDA and NIAAA. Therefore, many of the perspectives address a merger of NIDA and NIAAA or a nonstructural approach to increasing collaborations between these two institutes.

i. Arguments in Favor of a Structural Reorganization

Scientific Synergies. As noted above, emerging scientific research indicates that similar reward pathways underlie compulsive behavior and addiction. In addition, similar risk factors are associated with use and abuse of drugs and alcohol, and similar behavioral therapies and prevention strategies can be employed regardless of substance. Some stakeholders argue that a structural reorganization is the most effective way to capitalize on these synergies.

Given these scientific similarities, external analysts such as Lewin and Associates and the National Academies have questioned whether the current organization at NIH, with separate research institutes on drug (NIDA) and alcohol (NIAAA) use,

abuse, and addiction, provides the optimal infrastructure for supporting these areas of scientific research.

Underserved Patient Populations. Proponents of a structural reorganization have argued that segregating these disciplines creates gaps in addressing public health. Given that a high prevalence of individuals using drugs also use alcohol[10], proponents of a structural reorganization view the current organization with NIAAA and NIDA as insufficient to meet the needs of this population. For example, one NIDA Advisory Council member asked, "My patients have no problem mixing drugs and alcohol—why do you?"

Moreover, given that early risk factors for use are often burgeoning during adolescence, this population represents a key target for prevention and intervention strategies. Proponents of a structural reorganization stress that the current organizational structure does not meet the needs of the at-risk adolescent population sufficiently.

Impediments to Collaboration and Integration. Proponents of a structural reorganization cite cultural barriers as significant obstacles hindering effective communication and collaboration between the alcohol and drug abuse research communities. They argue that these hurdles can be overcome only through a structural merger of NIAAA and NIDA. For example, there are distinct professional societies for the two research communities and insufficient communication between them, despite areas of commonality.

Similarly, some stated that these cultural barriers create significant challenges to training early-stage investigators who are well-equipped to participate in interdisciplinary research teams. Structural reorganization was cited as an effective mechanism to enhance training and incentivize early-stage investigators to pursue the field of addiction research.

Given the large number of institutes and centers supporting relevant addiction research portfolios, some have argued that coordinating an initiative among so many institutes would be overly burdensome and would ultimately render the strategy ineffective. Moreover, these proponents argue that to more effectively streamline collaboration and maximize integration, the agency should establish a clear structural home for this research.

ii. Arguments in Favor of a Nonstructural Approach for Increasing Collaboration

Potential Loss of Research. Several researchers and constituency advocates, primarily from the alcohol research and treatment community, expressed

[10] Lawrence Tabak, April 28, 2009 presentation to the SMRB.

concern that merging NIAAA and NIDA could diminish the focus on (and funds for) alcohol research, resulting in the stagnation of discovery and oversight of critical end-stage organ pathology research. In part, this concern has been attributed to the differences in the budget of the two institutes: in fiscal year 2009, the NIAAA budget was $450,095,000, and the NIDA budget was $1,032,457,000. Subsequently in FY 2009, NIDA received 1,871 applications and funded 403 (a 21.5 percent success rate), while NIAAA received 811 applications and funded 191 (a 23.6 percent success rate). This discrepancy in budget and portfolio size perpetuates the fear of some that the larger institute will consume NIAAA in a structural merger of the two institutes.

In that same vein, numerous experts and stakeholders expressed concern that merging NIAAA and NIDA into a single addiction-focused institute could eradicate the portions of each portfolio not focused on addiction. For example, NIAAA funds research on the end-organ effects of alcohol, particularly the liver. Stakeholders underscored the potential loss that this research might sustain through a merger and argued that this issue should be a critical factor in the ultimate decision.

Establishment of a Research Dogma. Some individuals expressed concern that centralizing addiction research within a single institute could result in a research dogma, which could diminish the exploration of other mechanisms underlying this disease. They argued that it is inappropriate to constrict the focus of an issue as complex as addiction; potentially valuable insights might be lost when this research is constrained to a single vision and source of funding rather than two. Moreover, there are benefits to having multiple perspectives brought to bear on common questions. Functional integration around substance use, abuse, and addiction through increased coordination and collaboration has the added benefit of enhancing collaboration for all addiction research across NIH. For example, rather than focusing on structural reorganization of NIDA and NIAAA, a functional reorganization strategy could include components from NIMH, the National Institute of Neurological Disorders and Stroke (NINDS), the National Cancer Institute (NCI), and other institutes with relevant portfolios. This added benefit may be more difficult to achieve through a structural reorganization involving NIDA and NIAAA.

Examples of Current, Successful Collaborations. Examples of existing collaborations between the two institutes also were cited, as some argued that effective collaborative efforts were already facilitated and supported in this area. In fiscal year 2008, NIAAA and NIDA co-funded 13 grants. Among the common principal investigators, 112 received awards from both institutes. NIDA and NIAAA co-fund Collaborative Studies on Genetics of Alcoholism (COGA) and

National Epidemiological Survey on Alcohol and Related Conditions (NESARC), and NIAAA uses NIDA's Clinical Trials Network at times.

Licit versus Illicit Substances. Several stakeholders noted that NIAAA funds research concerning a legal substance, alcohol, and NIDA funds research concerning illicit drugs. Therefore, they argue that the two institutes should remain separate in order to maintain a consistent public health message with their respective target audiences. The fact that alcohol is also an illegal substance for individuals under the age of 21 complicates this argument. Concern also was expressed regarding the stigma that would be attached to alcohol use if it were combined with illicit substances.

IV. DELIBERATING ORGANIZATIONAL CHANGE FOR SUAA RESEARCH AT NIH

The discussion of whether to undertake major organizational change was informed by *Deliberating Organizational Change and Effectiveness,* a report developed by the SMRB Working Group on Deliberating Organizational Change and Effectiveness (DOCE) and approved by the full SMRB. The framework described in this report is to be used by the SMRB when considering organizational change at the NIH; the framework's fundamental premise is that any rationale for organizational change at NIH must be to improve NIH's ability to fulfill its mission. The framework elucidates three steps for contemplating organizational change at NIH: (1) assessing the need for change, (2) evaluating the options for change, and (3) navigating the change. In the following sections, the SUAA Working Group's findings regarding Steps 1 and 2 are described, including its assessment of the need for change in the organization of SUAA research at NIH and the evaluation of the options for organizational change. In light of the prospective nature of this work and of the group's recommendations, it would be premature to speculate how the agency should navigate organizational change.

A. Assessing the Need for Change

The existing body of research was important in the SUAA Working Group's assessment of the need for change, i.e., in completing Step 1 of the DOCE framework. In the DOCE report, five categories of issues that may prompt considerations of organizational change are described: (1) an immediate crisis, (2) unaddressed scientific opportunities, (3) changes in the scientific landscape, (4) evolving emergent public health needs, and (5) the need for improvements in quality and/or efficiency of research. The first criterion, likely the most straightforward to assess, is whether an immediate crisis threatens the ability of NIH to fulfill its mission. In

response to this question, the Working Group unanimously agreed that there is no crisis that threatens the agency's ability to fulfill its mission with respect to SUAA research. This finding was subsequently endorsed by the full SMRB.

The remaining four categories are a bit more complex to assess, but the SUAA Working Group did identify several areas of scientific inquiry not sufficiently addressed due to the limitations of the current organizational structure. Opportunities for enhancement or a more targeted approach included preventing adolescent use, abuse, and addiction; promoting an understanding of both alcohol and drug abuse as diseases; and understanding drug-drug interactions. Members also agreed that changes in the scientific landscape have enabled new opportunities for innovation and advancement that potentially could benefit from reorganizing SUAA research within NIH. In addition, advancements in a systems-level understanding of addiction warrant a joint approach for many aspects of SUAA research.

Looking forward, the Working Group also identified evolving public-health needs on the horizon that may create new challenges and opportunities that may be best faced by reorganizing existing components within NIH. These factors include populations suffering from co-morbid conditions associated with substance use, abuse, and addiction and the rise in other forms of addiction (e.g. gambling, food, sex). Also relevant to this discussion is the training of future generations of SUAA researchers and the effective dissemination of information. The Working Group agreed that two areas that could benefit from enhanced coordination are developing an integrated discipline of addiction research and strengthening cross-training across fields.

After thorough analyses of the data and extensive discussion, the SUAA Working Group unanimously agreed that the status quo is not ideal for fulfilling the NIH mission and optimizing SUAA research. In its subsequent deliberations, the full SMRB endorsed this finding of the SUAA Working Group, concluding that the current organization is neither optimal nor ideal.

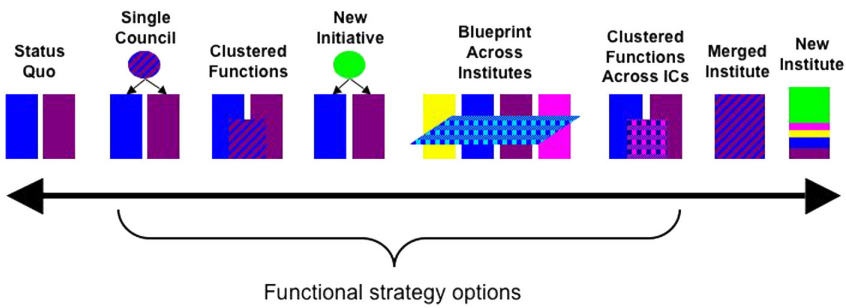
B. Evaluating the Options for Organization Change in SUAA Research at NIH

After assessing the need for organizational change in SUAA research at NIH, the Working Group concluded that the status quo is not ideal for fulfilling the NIH's mission and advancing research into substance use, abuse, and addiction, and organizational change is needed. Although initial discussions focused on two options–either leaving the institutes separate or merging them into one institute–the Working Group decided that it would be in the best interest of SUAA research to take a more holistic approach in examining potential options for reorganization. The SMRB subsequently affirmed this decision by the Working Group.

The options considered by the Working Group can be conceptualized along a spectrum of change, ranging from a variety of functional strategies through structural reorganization (see Figure 3). As defined in the SMRB's DOCE report, *functional* organizational change entails the implementation of new or different mechanisms for coordinating the work of existing components, usually with the aim of realizing some as of yet unrealized goal. Such mechanisms may take the form of committees, task forces, or consortia that bring together structural components around shared foci, activities, and goals. As such, they are flexible and have the potential to create and sustain new synergies. At NIH, there are nearly 40 working examples of functional strategies for organizational change. *Structural* organizational change, according to the DOCE report, entails the creation of new organizational components and/or the merger or elimination of existing components. The basic components of the NIH are its 27 institutes and centers. Issues under review include whether science and the public would be served best by merging NIAAA and NIDA or whether there are other functional approaches to organizational change that would catalyze greater synergy among the broad range of addiction sciences.

As depicted in Figure 3, a potential spectrum of options for reorganizing NIAAA and NIDA can range from maintaining the status quo (left) to merging the two into a single institute (right). One could also create a new addiction research institute with addiction elements of multiple institutes. In the middle are options for functional reorganization that require increased collaboration between independent institutes. Functional strategy options include a single advisory council for the two institutes or some shared functions, joint ventures, or a blueprint for research in some areas across the institutes.

Figure 3. Example of spectrum of options considered by the Working Group.



In evaluating the options for organizational change, the Working Group focused on and, with respect to the leading options, attempted to answer several questions, including:

- How can NIH increase synergy among researchers studying different facets of substance use, abuse, and addiction?
- How can NIH best promote the development of treatments for multiple addictions/co-morbidities?
- How can NIH ensure that all areas of addiction, including addictive behaviors such as smoking and gambling, receive appropriate scientific attention?
- How can organizational structure advance research on fundamental pathways underlying substance use and abuse, help develop new treatments for addiction, and help develop therapeutic applications of these substances?
- What are the strengths and weaknesses of various organizational options?
- Are other areas of research being examined for potential inclusion in a merged institute?
- Should the SMRB consider broadening the mission/scope of a merged institute focusing on drugs and alcohol to include addiction research more broadly?

V. SUAA WORKING GROUP RECOMMENDATIONS

- **Reject the Status Quo**

As previously stated, the members of the SUAA Working Group unanimously agreed that the status quo is not ideal for fulfilling the NIH mission and optimizing substance use, abuse, and addiction research at the NIH. Research has changed our understanding of substances of abuse, revealing that the while differences exist between and among alcohol, illicit drugs, and tobacco, all are likely undergirded by similar or common neurobiological pathways of response and reward. The structure of NIH should evolve accordingly, not simply as a response to new discoveries, but also to lead ongoing efforts to advance our understanding of the fundamental bases of one of our nation's most pressing public health problems. Specifically, NIH should act to bridge or dismantle barriers to collaboration in addiction-related research. While NIDA and NIAAA do collaborate on some addiction programs, research and public health needs will be served better if addiction-related programs across NIH work together more closely. The ideal solution will reduce siloing and capitalize on evolving synergies between and among addiction research programs.

B. Key Features of Reorganization

i. Integration of Addiction Research Portfolios across NIH

Based on close examination of the scientific opportunities and unmet public health needs cited by many of the experts consulted, the Working Group concluded that the scope of reorganization should be focused on addiction-related research and not restricted to opportunities in drug and alcohol research. The goal of reorganization should be to capitalize upon existing synergies while facilitating the identification of new areas of opportunity in addiction research.

In light of the diverse research funded across NIH, including substances (e.g., tobacco) and behaviors (e.g., gambling) with the potential for addiction, an emphasis on addiction research should include portfolios from many institutes and centers. For example, research into the neurological pathways of addiction conducted by NIMH and NINDS would be crucial to advancing an understanding of addiction and could be strengthened through enhanced collaborations. Likewise, NCI's addiction portfolio on tobacco-related research could make substantial contributions to these collaborative efforts, especially those targeted towards prevention and behavioral interventions. A reorganization effort confined to NIAAA and NIDA, while excluding these other addiction-related components of NIH research, would neither fully advance the science nor fully address the current opportunities and needs.

The mission of the reorganized entity should reflect the diverse array of substances (e.g., alcohol, cocaine, tobacco, food) and behaviors (e.g., gambling, exercise, sex) that have demonstrated the potential for compulsive use and abuse, along with the range of behavioral stages that can lead to the prevention or facilitation of compulsive use (e.g., abstinence, abuse, addiction, etc.). The mission statement should be defined clearly and should promote:

- A new and unified vision for effectively meeting currently unmet scientific opportunities and unmet public health needs in research on substances and behaviors with the potential for abuse and addiction;
- An interdisciplinary approach to advancing the research missions of both NIAAA and NIDA, in addition to other relevant NIH institutes and centers;
- Flexibility for new areas of study as new and unexpected scientific opportunities and public health needs emerge; and
- A multidisciplinary approach to training new investigators.

ii. Commitment by all Participants to the Success of the Reorganization

The success of any reorganization will depend decisively on the support and commitment of all participants—including the NIH Director, directors of relevant

institutes and centers, participating and contributing NIH staff, and the community of affected researchers and stakeholders. Furthermore, strong leadership is critical to identifying and establishing priorities and making decisions. Leaders also must be held accountable for the success of the effort.

A successful reorganization also will require a well-defined and supported structure, sufficiently articulated and organized to identify the collaborative goals inherent in addressing unmet scientific and public health needs. A loosely defined committee that meets infrequently is unlikely to achieve the goals outlined in this report. A stable, dedicated budget, staff, and resources also are essential to the success of any reorganization strategy.

iii. Functional Integration

In part for ease of presentation, discussions to this point have focused on a distinction between functional and structural options for reorganization. It is important to acknowledge that a successful structural reorganization strategy must be underpinned by effective functional integration within the new structure. A structural reorganization is not merely a combination of existing parts under a new heading. The successful structure will need to be characterized by shared goals; enhanced communication and collaboration; engagement and participation from all relevant parties; identification, creation, and sustention of new synergies; and cultural shifts needed to realize these elements. This type of functional integration among existing and new components will be necessary for the success of either type of reorganization strategy.

C. Two Options for Reorganization

SUAA Working Group members developed two options for reorganizing SUAA research at the NIH to maximize collaboration and facilitate progress in addiction research: (1) a single institute focused on addiction, to which all NIH addiction-related research would be relocated, or (2) a trans-NIH addiction program (like the Neuroscience Blueprint) with participation from all institutes and centers that fund addiction-related research. Although each option entails a certain degree of risk, each would yield a marked improvement over the status quo and could be successful with adequate support and leadership. Finally, the SUAA Working Group emphasized that, in accordance with the principles and framework enunciated in *Deliberating Organizational Change and Effectiveness,* the success of either option will depend upon the development and execution of a plan for rigorous, systematic evaluation based upon clear, sound metrics.

The two optimal options are described in this section. The following section provides a synthesis of the arguments in favor of each option.

i. Reorganization Option 1: Create a New Addiction Institute

The first option for advancing addiction research at NIH is to create a new institute devoted to addiction research. This new institute would integrate all relevant addiction research portfolios from NIAAA, NIDA, and other institutes at NIH. Non-addiction research portfolios currently held by NIAAA and NIDA would be transferred to other institutes as deemed appropriate, and the current NIAAA and NIDA would be dissolved. Funding for existing research should not be supplanted or reduced; rather, it should be relocated so that addiction-related programs are funded out of the addiction institute to achieve better integration and synergy across substance- and behavior-addiction research fields.

Research Portfolios. NIH should conduct an agency-wide portfolio analysis of intramural and extramural research to determine which addiction-related programs should be included in the new institute. This analysis should include addiction research and its relevant precursors regarding use and abuse. Examples include, but are not limited to, drug addiction research from NIDA, alcohol addiction research from NIAAA, tobacco addiction research from NCI and other relevant institutes and centers, and gambling addiction research from NIDA and NIMH—including relevant basic, prevention, treatment, behavior, and policy research. In addition, portfolio analysis of NIDA and NIAAA should identify non-addiction research, and these programs should be reassigned to alternative institutes or centers. For example, research on alcoholic liver disease could be reassigned to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and research on Fetal Alcohol Spectrum Disorders could be reassigned to the National Institute of Child Health and Human Development (NICHD).

Funding. In order to establish and fund a new addiction institute, Congress would need to authorize and appropriate its funding. Funding for all addiction-related research programs relocated from NIAAA, NIDA, and other institutes should be redirected to the new institute. Funding for non-addiction and end-organ research programs relocated from NIAAA and NIDA to other institutes and centers should be reassigned to their new institute. Total funding for research in a particular field should not be reduced.

Organizational structure. The new institute should consolidate structural components that are redundant across institutes and create new structural components necessary to support the newly defined mission.

Leadership. The NIH Director should form a search committee to identify, recruit, and hire a director for the new addiction institute. The new director should have a strong foundation in addiction research balanced across multiple

substances of abuse and compulsive behaviors. The new director also should have a clear understanding of the scientific opportunities and public-health needs in addiction research. The SUAA Working Group members recommend that the new director possess the confidence of NIAAA and NIDA staff, intra- and extramural researchers, and stakeholders.

Personnel. The new institute should be staffed by current NIAAA and NIDA personnel and by individuals from other institutes and centers (as necessary) to achieve the new mission or to address gaps in research.

Strategic plan. In combination, the new institute director and institute program staff should develop a strategic plan to advance addiction-related research. The strategic plan should be informed by the new mission statement, results of the NIH-wide portfolio analysis, NIAAA and NIDA Advisory Councils, NIAAA and NIDA intra- and extramural researchers, stakeholders, and the issues raised in this report.

Transition plan. Given the lengthy process that must be undertaken to appoint a new director, a transition committee should be established to make the innumerable decisions necessary to implement this reorganization option. This committee should develop a transition plan that outlines the process for writing the name and mission statement, determining which research portfolios should be included, developing the organizational structure, and establishing a timeline to ensure progress is made in a timely manner.

ii. Reorganization Option 2: Form a Trans-NIH Initiative on Addiction

The second reorganization option for advancing addiction research at NIH is to establish a trans-NIH collaborative initiative, similar to the NIH Blueprint for Neuroscience Research or the newly created Basic Behavioral and Social Science Opportunity Network (OppNet). All existing institutes would remain intact, but those with relevant addiction-related research portfolios would be integrated within the new program.

Research portfolio. Institutes with addiction-related research portfolios would participate in the new initiative and contribute to the integration of addiction research. NIH should conduct a portfolio analysis of extramural and intramural research to survey the current landscape of addiction research supported by NIH, in addition to identifying all relevant programs and research gaps.

Funding. Stable, dedicated funding is essential to the success of a multi-institute collaborative approach such as the one envisioned for addiction-related research. For the proposed strategy to be successful, each institute must include a substantial amount of its addiction portfolio funds; otherwise, the initiative will

have only marginal effects. It is the opinion of several Working Group members that the majority of each institute or center's addiction funds should be devoted to this effort. The SUAA Working Group recommended that the NIH Office of the Director also contribute to the initiative in order to supplement individual institute and center contributions and to demonstrate the NIH director's commitment to its success.

Organizational structure and leadership. A steering committee should be established to lead the new initiative. Members should include institute and center directors whose respective institutes have research portfolios that fall under the mission of the initiative. The steering committee should be co-chaired by four or five institute or center directors: NIAAA and NIDA each should have a permanent seat, while the remaining two or three seats should be rotated among the other steering committee members. Working groups or coordinating committees should be established to carry out the main work of the initiative—addressing, for example, specific areas of addiction research, strategic planning activities, and the development of an evaluation plan for the initiative. Subject matter experts from the participating institutes and centers should constitute these committees. Mechanisms should be put in place to ensure that the steering committee is held accountable for the success of the initiative.

Personnel. The new initiative should be staffed by NIAAA and NIDA personnel and by individuals from the other institutes and centers (as necessary) to achieve the new mission or to address gaps in research. The initiative should have dedicated staff for its day-to-day operations.

Strategic plan. The steering committee should develop a strategic plan to advance addiction-related research. The strategic plan should be informed by the new mission statement, results of the NIH-wide portfolio analysis, and the issues raised in this report. Public and stakeholder input will also be essential in developing the strategic plan.

Evaluation. Clear metrics should be established to determine whether the initiative is successful in achieving its mission. For example, clear and tangible outputs should be identified to measure collaborations, programs, activities, training opportunities, etc. The steering committee should use these results to refine its approach as necessary. It is critical that the steering committee have the authority and willingness to terminate efforts that are not successful. If a particular activity or program is not meeting intended goals, resources and attention should be redirected to activities that offer more promise.

D. Summary of Arguments in Support of Reorganization Options 1 and 2

Throughout their deliberations, members of the SUAA Working Group remained committed to their assessment that the status quo is no longer acceptable and that the science underlying SUAA research would benefit from reorganization in order to capitalize upon existing synergies and address unmet opportunities and needs. Despite this consensus, the group remained divided regarding the form that reorganization should take, with some members favoring the creation of a new institute focused on addiction (Option 1) and others favoring the formation of a trans-NIH initiative focused on addiction (Option 2).

The perspectives of the stakeholder communities (reflected in Section III.C. above) resonated with the Working Group. In addition to those perspectives, the following arguments in favor of either Option 1 or Option 2 arose in the context of Working Group discussions.

i. Arguments in Favor of Creating a New Institute Focused on Addiction (Option 1)

Members of the Working Group found the unaddressed scientific opportunities and unmet public health needs particularly compelling. Proponents of Option 1 strongly believe that the formation of a trans-NIH initiative would be insufficient and unsuccessful in advancing science around these unaddressed opportunities and unmet needs. They noted the stark divergence between the drug and alcohol research communities, which is mirrored in the separation of their respective scientific associations (The Research Society on Alcoholism and the College of Problems on Drug Dependence). Those in favor of Option 1 argued that this separation could only be remedied by merging the two fields and establishing a new institute.

Proponents of creating a new addiction institute argue that the existence of separate institutes for alcohol and drugs perpetuates the misconception, especially among youth, that alcohol is not really a drug. Therefore, one benefit of merging NIDA and NIAAA is to develop a clear public health message that alcohol has similar detrimental effects on the brain and body as illicit drugs.

Option 1 also would provide a highly visible home for addiction research at NIH. By creating a single institute, comprehensive training programs integrating both multi- and interdisciplinary approaches to addiction research could be developed and supported. Moreover, a visible "home" for this type of research would indicate stability and enhance the recruitment of new investigators to the field. Research on the effects of alcohol on multiple organ systems would be preserved and potentially enhanced by relocating this portfolio to institutes and centers possessing expertise in these relevant areas.

Finally, the Working Group members advocating for Option 1 were convinced that the effective promotion of research on polysubstance substance use, abuse, and addiction and a greater understanding of adolescent users is dependent on a unified structural framework in which substance- and behavior-based addiction research fields are thoroughly integrated.

All members acknowledged that success of a new institute would depend on leadership from the NIH director and the director of the new addiction institute. Success also will depend on participation, cooperation, and support from institute staff, intra- and extramural researchers, and stakeholders.

ii. Arguments in Favor of Forming a Trans-NIH Initiative Focused on Addiction (Option 2)

Working Group members who favored Option 2 agreed with the concerns identified by those in favor of Option 1, but they remained unconvinced that the creation of a new institute would produce significant change that could not be achieved through a trans-NIH initiative. In their view, a collaborative strategy deployed across the agency could address just as well the scientific opportunities and public-health needs, while minimizing the disruption and potential unintended consequences of a comprehensive structural reorganization. They pointed to evidence that other trans-NIH initiatives have worked in the past in other scientific areas, albeit with varying degrees of success (e.g., Neurosciences Blueprint, NIH Common Fund).

Advocates of forming a trans-NIH initiative expressed concern that creating a new institute might create research gaps in understanding alcohol's ubiquitous effects on the body and the unique factors contributing to its abuse. Option 2, however, would preserve the unique research conducted within each institute—for example, NIAAA's portfolio on the effects of alcohol on multiple organ targets—while capitalizing on synergies across the entirety of NIH. This approach also yields the added benefit of flexibility to reconfigure component programs and initiatives as needed in response to emerging scientific opportunities and public health needs.

An additional argument in favor of Option 2 is the recognition that the establishment of a new institute would constitute a significant undertaking, demanding considerable time and effort from the NIH director and NIH staff. The dissolution of NIAAA and NIDA and creation of the new institute described in Option 1 would cause considerable disruptions in the research community as well; although some of these disruptions would be short-term, there likely would be long-term implications of this change. Many Working Group members questioned whether the potential value gained from Option 1 was sufficient to warrant the pains that necessarily would accompany the creation of a new institute.

Although both Options 1 and 2 call for the inclusion of relevant programs across NIH, forming a trans-NIH initiative has the added benefit of an inherently interdisciplinary component. The creation of a new institute would include a variety of perspectives initially, with components and portfolios from various institutes and centers but, in the judgment of these Working Group members, likely would tend to engender a single discipline or culture within the agency. A trans-NIH initiative would draw continuously on a variety of perspectives, with representatives coming from institutes and centers across NIH and continuing to bring those unique perspectives to the table.

VI. SMRB CONCLUSIONS AND RECOMMENDATIONS

At its meeting on September 15, 2010, the SMRB received, discussed, and debated the final report of SUAA Working Group. In this process, the SMRB confirmed or endorsed certain findings by the Working Group. First, the SMRB concurred with the SUAA Working Group's finding that the current organization of SUAA research at NIH is not optimal for fulfilling the agency's mission or optimizing research in substance use, abuse, and addiction. All members of the SMRB strongly agreed that some form of reorganization is required in order to effectively capitalize upon existing and potential synergies, address scientific opportunities, meet public-health needs, and train the next generation of investigators. Second, the SMRB also endorsed the conclusion that such a reorganization should encompass all addiction-related research within the NIH and not just the programs of NIDA and NIAAA.

Presented with the two options for organizational change identified by the SUAA Working Group, the SMRB debated the advantages and disadvantages of each option. Ultimately, a majority of the Board (12 favored: 3 opposed; 1 abstained) voted to recommend that the NIH director not only consider, but also move to implement Option 1, the establishment of a new institute focusing on addiction-related research and public health initiatives. In the view of this majority, this option has the greater potential to improve and advance the conduct of SUAA research at NIH.

APPENDIX A

Speakers and Dates

APRIL 27–28, 2009

- Lawrence A. Tabak, D.D.S., Ph.D., Director, National Institute of Dental and Craniofacial Research, and Acting Deputy Director, NIH
- Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, NIH
- Kenneth R. Warren, Ph.D., Acting Director, National Institute on Alcohol Abuse and Alcoholism, NIH

SEPTEMBER 23, 2009

Prevention Specialists

- Nancy Freudenthal, First Lady of Wyoming
- Sheppard Kellam, M.D., Professor Emeritus, Johns Hopkins Bloomberg School of Public Health

Treatment Providers

- Herbert D. Kleber, M.D., Professor of Psychiatry, Columbia University College of Physicians and Surgeons, and Director, Division on Substance Abuse, New York State Psychiatric Institute
- Marc A. Schuckit, M.D., Professor of Psychiatry, University of California, San Diego; and Director, Alcohol Research Center and the Alcohol & Drug Treatment Program, VA San Diego Healthcare System

Patient Advocates

- Tom Donaldson, President, National Organization on Fetal Alcohol Syndrome
- Sue Rusche, President and CEO, National Families in Action; and Chief Architect, Parent Corps

Public Policy Specialists

- John Carnevale, Ph.D., Carnevale Associates, LLC

Cellular and Molecular Science

- Huda Akil, Ph.D., Professor and Senior Research Scientist, Department of Psychiatry, and Co-Director, Mental Health Research Institute, University of Michigan

- R. Adron Harris, Ph.D., June and J. Virgil Waggoner Chair in Molecular Biology, and Director, Waggoner Center for Alcohol and Addiction Research, University of Texas at Austin

Systems Science

- Michael Charness, M.D., Chief of Staff, VA Boston Healthcare System; Professor of Neurology and Faculty Associate Dean, Harvard Medical School; Assistant Dean, Boston University School of Medicine; and Scientific Director, NIAAA Consortium Initiative on Fetal Alcohol Spectrum Disorders
- Mary Jeanne Kreek, M.D., Professor and Head of Laboratory, Laboratory of the Biology of Addictive Diseases, Rockefeller University; and Senior Physician, Rockefeller University Hospital

Behavior Science

- Mark S. Goldman, Ph.D., Research Professor and Director, Alcohol and Substance Use Research Institute, University of South Florida
- Linda Porrino, Ph.D., Professor and Chair, Department of Physiology and Pharmacology, Director, Neuroimaging Laboratory, and Scientific Director, Center for the Neurobiological Investigation of Drug Abuse, Wake Forest University School of Medicine; and President, College on Problems of Drug Dependence

Treatment/Relapse

- Thomas R. Kosten, M.D., Waggoner Chair and Professor of Psychiatry, Pharmacology, and Neuroscience, Baylor College of Medicine; and Research Director, Substance Use Disorders Quality Enhancement Research Initiative, U.S. Department of Veterans Affairs
- Stephanie O'Malley, Ph.D., Professor and Director, Division of Substance Abuse Research, Department of Psychiatry, Yale University School of Medicine; and Director of Addiction Services, Connecticut Mental Health Center

Consequences

- Scott Friedman, M.D., Chief and Senior Attending Physician, Division of Liver Diseases, Mount Sinai School of Medicine
- David Vlahov, Ph.D., R.N., Director for the Center for Urban Epidemiologic Studies, New York Academy of Medicine; Professor of Clinical Epidemiology, Mailman School of Public Health at Columbia University; and Adjunct Professor of Epidemiology, Johns Hopkins Bloomberg School of Public Health

Policy Research

- Thomas Greenfield, Ph.D., Scientific Director, Alcohol Research Group, Public Health Institute; and Adjunct Clinical Faculty, Clinical Services Research Program, Department of Psychiatry, University of California, San Francisco
- David Rosenbloom, Ph.D., President and CEO, National Center on Addiction and Substance Abuse, Columbia University

OCTOBER 14, 2009

Judicial System

- Linda Chezem, J.D., Professor, Youth Development and Agricultural Education, College of Agriculture, Purdue University
- Pamela Rodriguez, President, TASC, Inc.

Academia

- Steven E. Hyman, M.D., Provost, Harvard University; Professor of Neurobiology, Harvard Medical School
- John H. Krystal, M.D., Deputy Chairman of Research, Department of Psychiatry, and Director, NIAAA Center for the Translational Neuroscience of Alcoholism, Yale School of Medicine; and Director, Clinical Neuroscience Division, National Center for PTSD, and Director, Alcohol Research Center, U.S. Department of Veterans Affairs

Industry

- Bankole Johnson, D.Sc., M.D., Ph.D., M.Phil., F.R.C.Psych., Chair of Psychiatric Medicine, Department of Psychiatry and Neurobehavioral Sciences, University of Virginia
- Steven M. Paul, M.D., Executive Vice President, Science and Technology, and President, Lilly Research Laboratories, Eli Lilly and Company

DECEMBER 22, 2009

- Enoch Gordis, M.D., Director, National Institute on Alcohol Abuse and Alcoholism, NIH, 1986–2001
- Alan Leshner, Ph.D., Director, National Institute on Drug Abuse, NIH, 1994–2001
- Ting-Kai Li, M.D., Director, National Institute on Alcohol Abuse and Alcoholism, NIH, 2002–2008

MARCH 10, 2010

- Hal G. Rainey, Ph.D., M.A., Alumni Foundation Distinguished Professor and Ph.D. Director, Department of Public Administration and Policy, University of Georgia

MAY 18, 2010

Members of the Community

- John Carnevale, Ph.D., President, Carnevale Associates, LLC
- Robert Carothers, Ph.D., J.D., Past President, University of Rhode Island
- Mimi Fleury, Chair, Substance Abuse Manual Committee; and President and Co-Founder, Community of Concern, Inc.
- Nancy Freudenthal, First Lady of Wyoming
- Flo Hilliard, M.S.H., Faculty Associate, Division of Continuing Studies, Professional Development and Applied Studies, University of Wisconsin–Madison
- Sue Rusche, Co-Founder, President, and CEO, National Families in Action; and Chief Architect, Parent Corps

Specialists on Behavior, Treatment, and Prevention

- Richard Catalano, Ph.D., Director, Social Development Research Group, School of Social Work, and Adjunct Professor of Education and Sociology, University of Washington
- Anita Smith Everett, M.D., Section Director and Assistant Professor, Community and General Psychiatry, Johns Hopkins Bayview Medical Center
- Peter Monti, Ph.D., Donald G. Millar Distinguished Professor of Alcohol and Addiction Studies, and Director, Center for Alcohol and Addiction Studies, Brown University
- Marc A. Schuckit, M.D., Distinguished Professor of Psychiatry, University of California, San Diego; and former Director, Alcohol Research Center and Alcohol & Drug Treatment Program, VA San Diego Healthcare System

Early Stage Investigators

- Laura M. Bohn, Ph.D., Associate Professor, Departments of Molecular Therapeutics and Neuroscience, The Scripps Research Institute
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- Charles P. O'Brien, M.D., Ph.D., Kenneth Appel Professor of Psychiatry, Department of Psychiatry, School of Medicine; and The Mahoney Institute of Neurological Sciences, University of Pennsylvania
- Adolf Pfefferbaum, M.D., Professor Emeritus, Department of Psychiatry and Behavioral Sciences, Stanford University; Senior Administrative Psychiatrist, California Division of Juvenile Justice; and Director, Neuroscience Program, SRI International
- Marc N. Potenza, M.D., Ph.D., Director, Problem Gambling Clinic, and Director, Women and Addictive Disorders Core, Women's Health Research, Yale University; and Associate Professor of Psychiatry and Child Study, Division of Substance Abuse, Yale School of Medicine
- Cary R. Savage, Ph.D., Director, Functional MRI, Hoglund Brain Imaging Center, and Professor, Department of Psychiatry and Behavioral Sciences, University of Kansas Medical Center

Reflections from Current NIDA and NIAAA Directors

- Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, NIH
- Kenneth R. Warren, Ph.D., Acting Director, National Institute on Alcohol Abuse and Alcoholism, NIH

APPENDIX B

NIAAA Advisory Council Resolution

Resolution of Council passed on 2-4-10: 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.

We wish to emphasize the following points in support of our position:

1. Alcohol is the only legal, socially acceptable, recreational drug; research on alcohol requires a different approach than research on drugs of abuse.

Alcohol use disorders (AUDs) arise in the context of widespread, healthy, social drinking. More than 120 million Americans use alcohol recreationally with clear social and health benefits, including a reduced risk for heart disease and stroke. In contrast, the recreational use of inhalants, nicotine, prescription drugs or illegal drugs is never socially acceptable or medically advisable. An important goal of alcohol research is to inform public policy and education to help limit drinking to safe levels in healthy adults and to encourage abstinence during pregnancy and before the age of 21. Abstinence or prohibition, the fundamental model of prevention for most drugs of abuse, is a proven, failed policy for the prevention of AUDs in adults, precisely because the healthy use of alcohol is ubiquitous in society. Thus, research in areas of prevention and social policy differs markedly for alcohol versus illicit drugs. The merger of NIDA and NIAAA would blur the clear and distinct public health message of each Institute, and weaken crucial alcohol-related public policy research.

2. Alcohol use disorders are different than drug addiction.

The genetics of alcoholism differs from the genetics of drug addiction. Prospective studies have shown that the sons of alcoholics are at greater risk for alcoholism than for drug dependence. Furthermore, a number of medications effective in the treatment of AUDs are not useful for the treatment of drug dependence and vice versa, suggesting that divergent pathways of medications development must be followed to address fundamental differences in the underlying pathophysiology of these disorders.

3. Alcohol misuse disorders produce enormous medical, economic, and social costs.

Even if most individuals recover spontaneously from AUDs, their misuse of alcohol results in enormous medical, economic, and societal costs. AUDs cost the nation $235 billion annually, nearly 80% more than the costs related to all other addictive drugs. AUDs result annually in more than 80,000 deaths, approximately 1/3 of all fatal car crashes, 1/2 of all homicides, 1/3 of all suicides, and 1/3 of all hospital admissions. Alcohol damages virtually every organ system. Fetal alcohol spectrum disorders are the most common non-genetic cause of mental and cognitive impairment, affecting up to 1 in 100 live births. Alcoholic liver disease, alone or in combination with viral hepatitis, is the most prevalent form of chronic liver disease in the Western world. Most research on fetal alcohol spectrum disorders, alcoholic liver disease, and alcohol-related organ toxicity is funded by NIAAA.

4. Much of the public health burden of alcohol use disorders is caused by the non-addictive use of alcohol.

The non-addictive use of alcohol accounts for much of the public health burden related to AUDs, including that related to fetal alcohol spectrum disorders, fatal car crashes, accidents, and homicides. On college campuses alone, alcohol use results annually in almost 2000 deaths, 100,000 sexual assaults, 600,000 injuries, and 700,000 assaults. For most college students, problematic drinking and its associated morbidity will not be solved by novel pharmacotherapies. Rather, psychosocial and public policy research championed by NIAAA is critical in the effort to reduce harmful college drinking.

5. The existence of certain commonalities in the brain pathways that mediate the rewarding effects of alcohol and other drugs of abuse does not justify the merger of NIAAA and NIDA.

Reward systems in the brain govern many motivated behaviors, including eating, drinking, romantic courtship, sex, music appreciation, and diverse positive social interactions. The fact that these neural circuits also contribute to the rewarding effects of alcohol and drugs of abuse does not justify merging NIAAA and NIDA. Likewise, the fact that dopamine is an important neurotransmitter in signaling reward associated with myriad motivational stimuli does not provide a strong rationale for merging Institutes. Dopamine systems are perturbed in Parkinson disease, schizophrenia, and childhood dystonia, yet no mega-merger is proposed for NINDS, NICHD, NIMH, NIAAA, and NIDA. In the same way, we do not advocate the merger of NIDDK, NIAAA and NIDA to study those elements of food addictions, alcoholism, and drug addiction that share similar brain pathways, or the merger of NIDA or NIAAA with NIMH to study psychiatric co-morbidity.

However, we do advocate enhanced collaboration among these Institutes to better understand how these disorders interact and overlap.

6. Most individuals with alcohol use disorders do not abuse other drugs.

NIAAA's study of more than 43,000 subjects demonstrated that most individuals with AUDs do not have mental health disorders and do not abuse other drugs. Although most individuals who abuse drugs also have AUDs, this subgroup comprises a minority of individuals with AUDs and contributes to a small share of the public health burden associated with AUDs. The large size of the population with AUDs who don't abuse other drugs and the enormous public health burden of their illness justify NIAAA's focused approach to research on AUDs, separate from drug dependence. The combined abuse of alcohol and drugs can be addressed through enhanced collaboration between NIAAA and NIDA. Likewise, the subgroup of individuals with AUDs and mental health disorders can be studied through enhanced collaboration between NIAAA and NIMH.

7. Alcohol differs from other drugs of abuse in the degree to which heavy use damages the brain and other organs.

Alcohol is particularly toxic to the brain and myriad organ systems, as well as to the developing fetus. The neurological disorders that result from alcohol neurotoxicity and concomitant malnutrition constitute a large and important public health problem. Alcohol damages multiple organ systems through common mechanisms of toxicity, including oxidative stress, the disruption of critical cell signaling systems, and the generation of toxic metabolites, cytokines, and chemokines. The coordinated study of these multiple organ toxicities is best suited to a single alcohol Institute.

8. A systems approach is essential to the study of alcohol's beneficial and adverse effects.

Alcohol affects the entire body, enhancing cardiovascular health with moderate use, and damaging multiple organs with heavy use. Alcohol-induced injury in one organ system, such as the gut, liver, or immune system, is inexorably linked to alterations in the structure and function of others, such as the brain. NIAAA recognizes that a systems biology approach is essential to study the universe of alcohol's beneficial and harmful interconnected effects on the brain and other organ systems. The merger of NIAAA with NIDA to form a new Institute focused on addiction would orphan and dissociate critical programs focused on alcohol and cardiovascular health, liver disease, pancreatitis, fetal alcohol spectrum disorders, immune disorders, myopathy, neuropathy, and brain disorders. Alcohol research clearly benefits greatly from the organizational integrity of a single Institute that focuses on all aspects of alcohol.

9. A merger will sacrifice the diverse approaches of two Institutes to addiction research.

The cornerstone of health research in the United States is the investigator initiated grant and the thousands of ideas generated by independent investigators. Even at the level of NIH Institutes, there are advantages to diversity in the evolution of scientific ideas. NIAAA has fostered an agile approach to medications development that benefits from its focus on a single drug, alcohol, and an integration of basic science research, translational research, and clinical trials using patients at an early stage of disease development. The product of this research is more than a dozen medications approved or under investigation for the treatment of AUDs. NIDA utilizes a clinical trials network that tests medications for diverse drugs of abuse in individuals with more advanced disease who are often recruited from the criminal justice system. The creation of a single, large Institute under the direction of a single director risks losing the diversity of approaches to the development of treatments for these conditions and the agility of NIAAA, as a small Institute, to adapt quickly in response to scientific opportunities.

10. The loss of an independent NIAAA will damage NIH's initiative on improving global health.

NIAAA is a leader among NIH Institutes in conducting global health initiatives. Foreign countries that cannot afford an alcohol Institute have looked to NIAAA for guidance in setting policy on the use and abuse of alcohol. A decision to abolish NIAAA would send a message to the global community that the United States devalues the effort to coordinate research and policy related to alcohol, the fifth leading cause of global death and disability.

11. The loss of an independent NIH Institute dedicated to alcohol research will discourage young scientists from entering the field.

NIAAA's emergence as an Institute brought the importance of alcohol-related health problems to national attention and signaled to researchers that alcohol research is an important public health endeavor and area of scientific inquiry. NIAAA has attracted some of the best and brightest investigators to the field. The loss of an independent Institute devoted to research on alcohol abuse and alcoholism will deter the recruitment of new researchers to the field.

12. What we stand to lose through the merger of NIAAA and NIDA is far more than what we stand to gain. What we stand to gain through merger can be accomplished through alternative approaches, including enhanced collaboration between NIAAA and NIDA.

Mergers of large organizations are traumatic, destabilizing, time-consuming, and

costly; therefore, we stand to lose time, personnel, resources, and mission focus. Mergers often result in organizations that are too large, inflexible, and unwieldy to respond quickly to changing opportunities and sacrifice the diversity of their parent organizations. Dissolving NIAAA into an Institute on addiction or drug use and abuse will compromise the integrated study of genetics, cell biology, organ systems, psychology, social systems, and public policy that characterizes NIAAA's coordinated approach to one of America's most important public health burdens. On the other hand, it is not clear what we stand to gain, either scientifically or organizationally, through a merger of NIDA and NIAAA that could not be accomplished through enhanced collaborations between the two Institutes and across NIH.

APPENDIX C

NIDA Advisory Council Resolution

Resolution of Council passed on 3-1-10: 15 "Approve"; 0 "Reject".

Whereas, the National Advisory Council of the National Institute on Drug Abuse (NIDA) is charged with advising and making recommendations to the Secretary of Health and Human Services and the Director, National Institute on Drug Abuse on matters related to the activities carried out by and through the Institute and the policies respecting these activities;

And Whereas, a drug is defined as an abusable chemical substance that alters living processes; and this includes cocaine, heroin, alcohol, marijuana, and other addictive drugs;

And Whereas, epidemiologic studies show that persons addicted to one drug are very vulnerable to addiction to other drugs;

And Whereas, drug abuse exacts a tremendous toll on US society annually including an economic burden of $600 billion in health, crime-related costs, and losses in productivity as well as the premature deaths of more than 500,000 Americans;

And Whereas, scientific research shows extensive biological a cross-drug commonalities in the causes, mechanisms, prevention, and treatment of drug addiction, regardless of which particular drug is considered;

And Whereas, a unified research focus on underlying causes, mechanisms, prevention, and treatment of drug addiction, regardless of the particular drug involved, is most likely to clarify similarities and differences among addictive drugs, to advance scientific knowledge, and to improve the public health;

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.

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