

**BACKGROUND AND TALKING POINTS
CONCERNING THE PROPOSAL TO CREATE A NEW
SUBSTANCE USE, ABUSE, AND ADDICTION
INSTITUTE AT NIH**

October 18, 2011

Background

In November of 2010, NIH's Scientific Management Review Board ("SMRB") recommended the creation of a new Institute focusing on substance use, abuse, and addiction research and related public health initiatives. This new Institute would integrate research portfolios from NIAAA, NIDA, and other NIH Institutes and Centers. Upon receipt of this recommendation, Director Collins requested NIH Principal Deputy Director Lawrence A. Tabak and NIAMSD Director Stephen I. Katz to assemble a task force of experts from *within* NIH to review all of NIH's 27 Institutes and Centers and make recommendations as to substance use, abuse, and addiction research programs which should be imported into the new Institute and which current NIAAA and NIDA programs should be exported to other NIH entities. Initially, Dr. Tabak's task force was targeted to produce a "straw model" of the new institute by mid-summer 2011 with a final recommendation to NIH Director Collins later in the year. However, at the June 9, 2011 meeting of the NIAAA Council Dr. Tabak announced that the "stand up" of the new addiction institute would be delayed until October 2013. He also announced a series of procedural steps leading to the establishment of the new institute:

- June 2011-Fall 2012: The SUAA Task Force and a NIAAA/NIDA intramural integration working group will conduct a portfolio analysis of all the relevant grants, cooperative agreements, contracts, and intramural research projects in all relevant institutes and centers and produce a Portfolio Integration Plan. A Scientific Strategic Plan will also be developed with input from stakeholders.
- Fall of 2012: The Scientific Strategic Plan and Portfolio Integration Plan will be published for public comment.
- December 2012: Final recommendations for the new institute will be sent to NIH Director.
- January-February 2013: Decisions on the Scientific Strategic Plan and the Portfolio Integration Plan will be made for inclusion in the President's FY 2014 budget; implementation of portions of the Scientific Strategic Plan that are not dependent on reorganization will begin before that time.
- October 2013: The new institute of will become effective.

Talking Points

1. **There is no mission statement for the proposed new institute.** In the absence of a cogent statement of the purpose of the new institute, there is no basis for deciding which research portfolios should be retained in the new entity, which should be exported to other NIH institutes and centers, and which portfolios of other institutes and centers should be imported into the new institute. Without a clear and comprehensive explication of the guiding principles for the proposed institute, it is difficult to see how the science in this domain will be advanced. The principles should be developed by experts in the field *before* portfolio reviews are undertaken, *not in tandem with the portfolio reassignment process*. If there are no pre-established principles, it is also highly likely that critical research initiatives will be compromised or lost, important research synergies disrupted, and research portfolios reassigned in a way which impedes their productivity.

2. **Despite being required by the NIH Reform Act of 2006, no analysis of the budgetary and operation consequences of the proposed institute has been conducted and estimate of the level of resources needed to establish the new institute has been made.** When Congress established the SMRB in the NIH Reform Act, it specifically required that “for any proposal for organizational changes to which the Board gives significant consideration as a possible recommendation”, the Board must provide information “analyzing the budgetary and operational consequences of the proposed changes”; “estimating the level of resources needed to implement the proposed changes”; and “assuming the proposed changes will be made and making a recommendation for the allocation of resources of NIH among the national research institutes and national centers”. None of these critical Congressionally-mandated requirements have been met.

3. **Restructuring to create a new institute will be disruptive and costly with little or no countervailing benefit.** The plan to create a new institute” would not only dissolve NIAAA and NIDA, but would also transfer portions of other institutes to the newly created institute. In addition, certain research initiatives of NIAAA and NIDA will be transplanted to existing NIH institutes. This process will be extensive, destabilizing, time-consuming, and costly, resulting in substantial lost time, personnel, resources, and mission focus. Furthermore, all structural reorganizations have upfront costs which will produce nothing by way of research effectiveness or efficiency. This problem is exacerbated by the absence of a mission statement and the failure to conduct statutorily-required budgetary and operational analyses. At a time when all federal agencies including NIH are facing possible deep funding reductions, the creation of a new institute under could well result in less effective research. In contrast, efforts to achieve greater functional integration of NIAAA and NIDA may make far more fiscal and scientific sense. Indeed, it is noteworthy that the two institutes are already aggressively pursuing functional collaborations to enhance, facilitate, and leverage research in numerous areas.

4. **The proposed reorganization will deny the American public an institute that is exclusively dedicated to addressing a major public health problem.** Misuse of alcohol costs the nation \$235 billion annually, and results in more than 80,000 deaths each year. It is the cause of approximately one-third of all fatal car crashes, one-half of all homicides, a third of all suicides, and one third 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. The

magnitude of the burden borne by the American public related to the use and abuse of alcohol more than justifies the preservation of a single institute devoted to the integrated study of these problems.

5. **The proposed new institute” may not address the health and social consequences of the majority who use alcohol.** Alcohol is a socially acceptable drug and more than 120 million Americans use it recreationally with clear social and health benefits, including a reduced risk for heart disease and stroke. 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. These critical missions may be lost or minimized by an institute whose focus extends far beyond alcohol, to the detriment of the health of the majority of Americans who use alcohol socially, or have non-addictive alcohol use disorders.
6. **Dissolution of the NIAAA will destroy its systems approach that has been essential to the study of alcohol’s beneficial and adverse effects.** Alcohol affects the entire body, enhancing cardiovascular health with moderate use, but 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 other organs, including the brain. NIAAA has fostered a systems biology approach to study alcohol’s beneficial and harmful interconnected effects on the brain and other organ systems. The formation of a new institute with an extensive new mandate covering a broad range of substances may well orphan and dismember productive research programs focused on alcohol and cardiovascular health, liver disease, pancreatitis, fetal alcohol spectrum disorders, immune disorders, and disorders of the nervous system. Importantly, it may remove the “systems approach”; alcohol research and its application to public health issues benefits greatly from this organizational integrity of a single institute that focuses on all aspects of alcohol and health. This systems integration would be lost by the proposed reorganization and the resulting human and economic cost would be significant.
7. **A focused approach to research on AUDs in a single institute is well-justified because 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.