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Scientific Management Review Board
Working Group Deliberating Organizational Change
Substance Use, Abuse and Addiction

Subject: Support of the proposed merger of the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Dear Review Board Chair and Members of the Subcommittee:

I am writing to comment on the proposed merger of NIDA and NIAAA. I have reviewed many of the comments and discussed this topic with colleagues for years. I strongly support a merger that I feel is long overdue. The cautionary comments of organizations such as the American Psychological Association, and those issued by many individuals, are important to consider but should not be considered insurmountable obstacles. In particular, the challenges of accomplishing the merger without severe adverse impact to advancing the science pertaining to the unique challenges posed by alcohol use disorders must be considered. Not surprisingly, organizations that are focused on alcohol fear that with a merger, alcohol will be treated as "just another drug" since it will no longer be the focus of an entire NIH institute. They are also concerned, about total resources for alcohol research and on this count they are right to be concerned and I hope that increased efficiency does not translate to elimination of promising areas of research. Nonetheless, from a pharmacological and behavioral pharmacological perspective, alcohol is one drug among many addictive drugs and the disease of alcohol dependence is characterized by generally similar symptoms as dependence to cocaine, morphine and nicotine. Similarly, prevention and treatment of alcohol abuse and dependence are not only guided by similar principles, they are increasingly intertwined as alcohol use disorders tend to precede and generally go hand-in-hand with other substance use disorders. Therefore, from the perspectives of pharmacology, prevention, treatment, and public health policy, there is no justification for the schism created by the two distinct institutes. Furthermore, the merger has the potential to contribute to more rapid advances in the understanding of the etiology of substance abuse disorders in general and thereby contribute to stronger advances in prevention and treatment interventions.

My views on this go back to my own training in psychopharmacology which began in the early 1970s when NIMH as the umbrella institute for alcohol and other drug research was being replaced by NIAAA then NIDA. This reorganization was probably more enthusiastically accepted by researchers because it inevitably meant a larger total pool of resources, in part because it was understood there would be redundancies in funding the same types of research across the two institutes. For example, successful grantees such as my own mentors achieved portfolios including both NIAAA and NIDA funded research – in some cases for very similar research programs. It was also well understood that the main drivers of the separation of alcohol from other drugs, were social and political and not pharmacological. The

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social divides ran deep and included key members of Congress who supported the division, scientific organizations such as the National Council on Alcoholism which awarded me a fellowship, and many treatment focused organizations representing individuals whose primary substance-related problem was alcohol. These social divides still exist, although probably to a lesser extent, and the merger must be sensitive to this to minimize opposition that could impede the efforts and progress toward an eventually well-accepted merger.

Raising social issues is not intended to imply that all of the scientific and public health issues regarding alcohol abuse were identical to those pertaining to other drugs. In fact, each drug class poses unique issues which must be addressed by research and public health policy. Avram Goldstein's classic 1994 book, "Addiction: From Biology to Social Policy" delineated various drug classes with respect to pharmacology and social policy while keeping them under the single tent of addicting drugs. A major benefit of this approach was that lessons learned from each type of addiction contributed to the understanding of the others. This is also true of the many types of cancer addressed by NCI, the various types of cardiovascular disease addressed by NHLBI, the several types of pediatric disorders addressed by NICHD and so forth, but it would be difficult to persuasively argue that these institutes should be divided into multiple institutes focusing on subtypes of disorders. It might even be argued that social considerations were more justifiably given stronger weight in the 1970s, but today, the intertwining of alcohol use, abuse and addiction, with other drug used disorders is typical, and the commonalities in methods of study, treatment, prevention, and mechanisms underlying vulnerability to addiction across alcohol, tobacco and other substances greatly outweigh the differences.

My greatest concerns are that important but relatively small pockets of scientific focus could disappear and that areas that should be of greater focus will face still greater obstacles in developing funding support. For example, it appears that NIAAA has dedicated proportionally more resources to the study of social, behavioral and marketing forces, as determinants of patterns of use and addiction, and as potential targets for prevention and treatment interventions. Such forces are undoubtedly enormously important in the abuse of illicit drugs, and probably to an even greater extent in tobacco addiction in the increase in prescription drug abuse. This is an example in which the merger would impair progress if such research that now has greater support by NIAAA was reduced; conversely, progress in combating alcohol as well as other drug use disorders might be improved by strengthening such research with respect to drugs in general and not just alcohol.

Similarly, although the primary manifestation of substance use disorders are behavioral, behavioral research seems to have an uphill battle in its justification in either institute but has probably fared better at NIAAA over the decades. Ensuring a strong focus on behavioral determinants and behavior focused interventions for substance abuse in general should be of broad importance to reducing the prevalence and adverse consequences of use of alcohol, cocaine, morphine, nicotine, and other addictive drugs.

Another area of concern is that support for diversity in researchers from the perspectives of gender, ethnicity and other factors will suffer. A number of years ago, my colleagues and I worked to establish greater diversity in substance abuse researchers arguing that greater diversity was vital to increase the excellence, relevance, and process of research. Of course it is also the right thing to do from perspectives of humanity, fairness and our Constitution, but we argued that it was a tangible path toward stronger science and improved public health progress (Henningfield, J.E., Singleton, E.G. and Cadet, J.L. Why we need increased ethnic diversity among drug dependence researchers. *Drug and Alcohol Dependence*, 35: 262-262, 1994). I think it is possible that such a merger could accelerate progress towards greater diversity in the portfolio of researchers, but if this is not an explicit goal, the outcome could be retrenchment.

My main advice in the merger is that the success or failure will be determined heavily by the details of the process because validation measured by scientific progress and public health benefit may take many years to assess. A corollary is that a misguided process that lacks the means of monitoring interim consequences, desired and undesired, could impair research progress and public health benefit. Therefore, the process should be guided and facilitated by an independent advisory board to help resolve the many disputes that exist now and will continue to emerge for many years to come. This process must address the entire research portfolio of each institute and work to ensure that in the reduction of redundancy, vital areas of research, and promising researchers are not lost. The process must find means to give fair hearings to program areas in which existing redundancies mean that consolidation and reduction of the total funding to those areas will occur. Although this probably cannot be achieved without some loss to arguably strong research programs, minimizing the loss of outstanding and emerging investigators is vital in the long run.

I raise the foregoing issues and concerns, not as obstacles to the merger, but rather as examples of a few of the many challenges that could be addressed by an orderly and well planned transition process. The goal should be a stronger NIH contribution to developing the science foundation for all substance use disorders, thereby providing a stronger foundation for prevention and treatment interventions.

In developing the process, it could be useful to examine mergers of other types of organizations including airlines, automobile manufacturers, health care providers, and other organizations for lessons in how to maximize the intended benefits including productivity, excellence, relevance, and efficiency. Conversely there are plenty of lessons available on approaches that carry greater risks of generating unintended consequences.

Another source of guidance that might be considered is FDA's evolving approach to risk management which is an approach to finding a path to market for drugs that offer benefits but which also carry risks that are not adequately addressed by the standard approval process. The basic concepts of FDA risk management seem highly applicable and flow as follows:

(1) Identify the intended benefits while thoroughly exploring and bringing to light every conceivable unintended consequence.

(2) Design the strategy in explicit effort to minimize unintended consequences while providing a pathway to benefits. This would call for complete transparency in the priority setting process as well as in justification of the specific means to achieve the desired ends.

(3) Assume that unintended consequences will emerge and include mechanisms for quick and accurate detection of such problems on a real time basis, probably with quarterly report. This will enable unintended consequences to be addressed in a timely basis and not in a time frame so slow that promising investigators migrate to other areas of research and potentially vital programs are lost.

(4) Include mechanisms for program and strategy adjustment (referred to as "interventions" in drug regulation) to address unintended consequences and maximize benefits.

The other way FDA's model is relevant to the merger is that the model is intended to cover the "life-cycle" of the drug. That is, the premise is that the process should be in place long term. If such an approach is implemented I believe it is likely to lead to discoveries and advances that may be applied to other NIH institutes to increase their intended benefits and to detect and address their deficiencies. Said another way, the challenges posed by an effective merger probably overlap with the challenges in keeping all NIH institutes vitalized, productive and relevant to the public health issues that they are intended to address.

In conclusion, I strongly support the merger of NIDA and NIAAA. There are challenges and barriers that will need to be clearly elucidated and addressed through a constructive and transparent process. This will include identification, not only of major priorities, but also of those small areas of research that are already struggling and which may be lost without some attention. The overall goals of a merged institute that is more productive, more relevant to public health, and sets ever increasing standards for excellence should be achievable but the details of the process and mechanisms of oversight and recourse will be most vital.

Sincerely,

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