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American Association for
the Study of Liver Diseases

March 30, 2009

Norman R. Augustine, Chair
Scientific Management Review Board
Office of the Director
National Institutes of Health, Building 1
Bethesda, MD 20892

Dear Mr. Augustine:

We are writing to respectfully request the opportunity for Gyongyi Szabo, M.D., Ph.D. to present testimony – both in person and in writing – at the meeting of the Scientific Management Review Board (SMRB) that is schedule to occur on April 28, 2009 with regard to whether or not the SMRB should consider the issues surrounding a merger of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA).

As you may know, the American Association for the Study of Liver Diseases (AASLD) is the leading international organization of scientists and healthcare professionals committed to preventing and curing liver disease. We foster research that leads to improved treatment options for millions of liver disease patients. We advance the science and the practice of hepatology, liver transplantation, and hepatobiliary surgery through educational conferences, training programs, professional publications, and partnerships with government agencies and sister societies.

Dr. Szabo, who is a leading researcher and a Professor at the University of Massachusetts Medical School with faculty appointments in Gastroenterology and Medicine, as well as the Chair of the AASLD's NIH Liaison Committee, will testify with regard to the likely impact on the science of liver-related alcohol and drug abuse research that would result from the merger going forward. Further she will testify about the chilling effect that will certainly occur during the months or years during which this merger would be considered on both new and experienced investigators in liver research.

We believe that the SMRB has a valuable contribution to make with regard to assuring that every taxpayer dollar spent at the National Institutes of Health is done so efficiently and effectively, so as to maximize the scientific benefit to the American people. We believe that Dr. Szabo's testimony will make a significant contribution to

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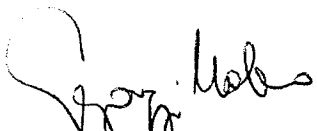
that work and would welcome the opportunity to work closely with the Board in the days and months ahead.

If you need further information about Dr. Szabo or about the AASLD, please contact Sherrie Cathcart, our Executive Director, at 703-299-9766 or at scathcart@aasld.org. Thank you for your consideration.

Sincerely,

Scott Friedman, MD
President



Gyongyi Szabo, MD, PhD
Chair, NIH Liaison Committee

AMERICAN
PSYCHOLOGICAL
ASSOCIATION

February 23, 2009

Norman R. Augustine, Chair
Strategic Management Review Board
Office of the Director
National Institutes of Health, Building 1
Bethesda, MD 20892

Dear Mr. Augustine:

I am writing with regard to the agenda for the Strategic Management Review Board (SMRB) meeting scheduled for April 27-28, 2009. With respect to one of the anticipated agenda items, the potential merger of the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), it is our understanding that the NIH Acting Deputy Director Dr. Lawrence Tabak will provide an overview of the issue and then the two institute directors will provide presentations about their respective institutes. During Dr. Tabak's presentations at the recent NIDA and NIAAA Advisory Council meetings, he explained that the SMRB will take a deliberative approach in examining the research portfolio and organizational structure of the NIH at the upcoming meeting.

The American Psychological Association (APA) would appreciate the opportunity to provide commentary at this first meeting, though we understand that the meeting is only intended to help the SMRB decide whether to take up the issues related to a potential merger. We believe APA has a unique perspective to bring to bear on this matter. NIDA and NIAAA have demonstrated a long commitment to psychological research and these two institutes stand out at NIH in that regard. In absolute dollars, NIDA funds more behavioral and social science research than any other NIH institute; and while smaller, NIAAA spends nearly half of its budget on behavioral and social science research. So the potential merger of these institutes is of immense interest to the psychological science community.

Not surprisingly, psychological scientists serve in leadership positions in the three major academic organizations dedicated to substance use research as: Past-President and President-elect of the College on Problems of Drug Dependence; President of the Research Society on Alcoholism; and Past President and President-elect of the Society for Research on Nicotine and Tobacco. In addition, over 2,000 APA members demonstrate their commitment to substance use research through their membership in our

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Norman B. Anderson, Ph.D.
*Chief Executive Officer and*
*Executive Vice President*

Divisions of Psychopharmacology and Substance Abuse (Division 28) and Addictions (Division 50).

Further, psychologists are involved at every level of the research enterprise -- whether studying gene/environment interactions in the treatment of nicotine addiction; developing interventions to counter the consequences of perinatal alcohol use; developing behavioral treatments for dependence on drugs, like methamphetamine, for which no pharmacotherapy currently exists; or evaluating pharmacotherapies for the treatment of opiate and alcohol dependence. Beyond the conduct of research, tens of thousands of psychologists use the results of NIAAA and NIDA funded research to treat clients with substance use disorders in clinical settings across the United States.

Given the primacy of psychology both in the conduct of substance use research and in the practical use of the results, we believe the SMRB would benefit greatly from a briefing that would include the multiple perspectives of psychological science related to a potential merger of NIDA and NIAAA. Therefore, APA would welcome the opportunity for a representative of APA to address the Board at its April meeting.

While we appreciate the role of the SMRB in evaluating efficiencies for the NIH, among the issues we would like to comment on include: 1) our concerns that a discussion of the proposed merger is ill-timed in the absence of a DHHS Secretary, a Director of the NIH, and a Director of the NIAAA; 2) any merger of institutes should include a guarantee that the overall quality of, and funding levels for, substance use research would not suffer; and 3) within any discussion of a merger, the SMRB must also consider the overall allocation of NIH resources with respect to the public health consequences of alcohol, tobacco, and illicit drug use.

Thank you in advance for your consideration and response to this request. If you have any questions or would like any additional information, please contact Dr. Geoff Mumford, who directs our Science Government Relations Office, at gmumford@apa.org or at (202) 336-6067.

Sincerely,

Norman B. Anderson, Ph.D.
Chief Executive Officer

cc: Dr. Raynard Kington
Dr. Lawrence Tabak
Rep. Henry Waxman
Sen. Ted Kennedy

AMERICAN
PSYCHOLOGICAL
ASSOCIATION

Science Directorate

Statement of Dr. Steven Breckler before the Scientific Management Review Board
April 28, 2009

Mr. Chairman and members of the Board, my name is Steve Breckler and I am Executive Director for Science at the American Psychological Association. Thank you for the opportunity to speak with you today about the question of whether or not a merger of NIAAA and NIDA should be studied. Psychological scientists have been intimately involved in the study of alcohol, tobacco and illicit substance use at many levels. In his letter of February 23, APA's CEO, Dr. Norman Anderson, outlined the role of psychologists in these areas. I believe you have that letter in your preparation materials so I won't elaborate further.

The American Psychological Association fully supports the assertion that any proposed consolidation of NIH institutes or centers should be driven by scientific considerations. Because this is the first meeting of the Board, we believe it is important that any merger discussion be framed with the intent to "do no harm". The approach should demonstrate how and why the research would be better if institutes were consolidated. If there are administrative cost savings anticipated with a merger, the Board must be vigilant in asking whether the savings are to be achieved at the expense of the research.

We know that the reorganization of NIH has been examined previously. Indeed, the idea of studying this particular merger was recommended by a National Academy of Sciences report in 2003. It is now six years later, but much of the insight of that report is still relevant. In summarizing the response to its charge, the committee acknowledged that "...both the nature of the charge and the 1-year period allowed for deliberations put important constraints on the development, character and scope of the recommendations that could be credibly put forward." That's why the Academy report recommended an "investigative committee", in anticipation of this very Board which was created as part of the NIH reauthorization act of 2006. The intent is to engage in regular, thoughtful review and deliberation of organizational, budgetary and operational issues that might improve the function of NIH.

The Academy's 2003 report provided some examples of what an investigative committee might do. Importantly, one of those was "Gathering input and opinion from the IC Directors...". This strikes us as a reasonable process recommendation, and raises for us an important question: Although nine institutes and centers are represented here, why would the SMRB initiate such a study at a point in time when neither NIH nor NIAAA have permanent leadership? Although the Board is charged with reporting recommendations to the NIH Director, as yesterday's discussion demonstrated, the NIH Director is clearly meant to exercise an active role in the deliberations of the SMRB. Might it not be wiser to wait until those important positions are filled before taking up the question before you now?

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The 2003 study also suggested examining a merger of NHGRI and NIGMS, but acknowledged that the Committee "...did not have the time or opportunity to review the merits of all such proposals to the extent that they deserve". Yesterday, the Board received a presentation summarizing the 2003 report and that report produced a number of valuable recommendations that have already been implemented but I'd note that the actual report gave equal weight to the proposed NIDA-NIAAA and NHGRI-NIGMS mergers, yet the latter appeared to be given short shrift yesterday and there was no discussion of why the Board agenda was favoring one over the other. With respect to the proposed NIAAA and NIDA merger, the 2003 report stated that "the broader scientific relationship and physical location of these two institutes with other neurosciences institutes (especially NIMH and NINDS) should also be considered." We found it noteworthy that Mr. Augustine added a third, impromptu, agenda item for consideration: If NIH didn't exist at all how would you design an organization to do what NIH does from ground zero? Now might be the time to do that, a task that the NAS committee admittedly did not have time to do, by taking a fresh look at the entire network of NIH institutes and centers rather than focusing on just one pair of institutes.

From a scientific perspective, we understand why the Board might want to focus on a possible merger of NIAAA and NIDA. They appear to share missions and foci that make them logical candidates for a merger. This is where the broader NIH context really needs to be taken into consideration. The value of the NIH model of multiple institutes is that they support diverse approaches to understanding interrelated problems. For example, although NIDA supports the lion's share of NIH research on tobacco use and smoking, NCI has a substantial tobacco research portfolio too. If an "addictions" institute were to be created out of the merger of NIAAA and NIDA, would the NCI tobacco research portfolio move there as well? The point is that the contemplation of a merger between two institutes is likely to have far broader implications across NIH, and that needs to be anticipated before going down this road.

I know that you do not need to be reminded of the NIH mission, which includes the support of "...science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability." From a public health perspective, a study such as the one you now contemplate would require a thorough re-examination of how the current allocation of NIH research resources maps onto the leading causes of morbidity and mortality. Alcohol and tobacco dependence are among the leading causes of death and disability, and so you will need to anticipate how such a study might have broad ramifications for the apportionment of funding to the disadvantage of many other institutes and centers across NIH. On the surface, the proposed study may seem straight forward and focused, but in fact it may be the tip of the proverbial iceberg.

We know that the Board is taking their charge very seriously in making a decision about the proposed study. For APA, it is the details, the priority of the research, and leadership that will make a merger successful or have a detrimental effect. Unless the scientific benefits to a merger are real and measurable, they may not justify the risks to the budget and support we know exists now. So the question we'd ask the Board is, do they really have enough information to invest their valuable time and resources into the consideration of a selective merger of any two institutes to the exclusion of others or other potential organizational constructs that should be the Boards primary focus?

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April 27, 2009

Norman R. Augustine, Chair
Scientific Management Review Board
Office of the Director
National Institutes of Health, Building 1
Bethesda, MD 20892

Dear Mr. Augustine,

I am writing in regard to the agenda for the April 27-28 Scientific Management Review Board (SMRB) meeting. I am Chair of the Friends of NIAAA, an organization created to support the mission and goals of the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Our coalition represents multiple scientific and professional organizations and community advocacy groups dedicated to the prevention and treatment of alcohol abuse and dependence, as well as to the study and treatment of the various consequences related to excessive and problematic use of alcohol. As such, we are very concerned about any initiatives that would threaten or interfere with the broad scope of research and science needed to address alcohol problems in our society.

We would like to comment on the agenda item before the SMRB regarding the potential merger of the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism. We understand that the agenda item proposes that the SMRB initiate a study of the potential merger that would result in recommendations. Although there may be some potential benefits, the Friends of NIAAA believe believes that the unique nature of alcohol makes the potential merger of NIAAA and NIDA a threat to current and future science, policy and research initiatives of the agency.

We understand that there are some important cross cutting scientific issues between alcohol and drug abuse, ranging from genetics to community prevention and intervention approaches. However, alcohol differs dramatically from drugs of abuse in many critical areas, particularly with regard to control and management of distribution and use. Varying levels of legal and illegal use and the vast range of consequences where alcohol plays a role, in terms of threats to the health and well-being of society, also make alcohol unique. We believe that this uniqueness deserves a special focus within the National Institutes of Health (NIH) and therefore respectfully request that the Board decline the opportunity to take further action on the merger. An amalgamation of research and policy concerns about various substances and other addictive behaviors seems to

represent a leveling process that could reduce research funding in ways that would be detrimental to the vast range of concerns represented by our constituent organizations.

This topic has been proposed and studied several times already and these discussions led to a reaffirmation of the need for separate institutes. We are certain that the currently proposed study will result in the same conclusions.

If the board determines that a study is necessary to fulfill the mission of the congressional mandate given to NIH, our objection is that the timing of such a study is problematic and prejudicial to NIAAA. Currently there is no permanent director of NIH or NIAAA. This study would need the input of a permanent director who has a vision of the future as well as a perspective on the past. Without this input the study cannot estimate potential impact on the mission of NIAAA. We strongly urge you to postpone such a study until these positions are filled and the community concerned with alcohol research, policy and practice is represented by a champion within the agency. This is not to place in doubt the competence of the interim leadership, but because there is a great difference in the perceived and real influence of interim versus permanent leadership.

In closing, we again urge you to consider our request to decline to study the merger of the NIDA and NIAAA. At the very least, we urge the Board to defer the study until leadership that would ensure a fair and full examination of the potential risks and benefits of such a merger is in place. We recognize the importance of your mission and the need to ensure that NIH is an effective, efficient and visionary organization that brings science to bear on health concerns of our nation. However, we do not believe that a study of this merger would be the best way to accomplish your mission.

Respectfully,

Carlo C. DiClemente, Ph.D.
Chair
Friends of NIAAA

The following Groups have agreed to co-sign this letter:

American Association for the Study of Liver Diseases
American College of Obstetricians and Gynecologists
Community of Concern
National Organization on Fetal Alcohol Syndrome
Research Society on Alcoholism

WRITTEN STATEMENT

SUBMITTED BY

**SCOTT FRIEDMAN, MD**

MOUNT SINAI SCHOOL OF MEDICINE

AND

**GYONGYI SZABO, MD, PhD**

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL

ON BEHALF OF THE

**AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES**

ALEXANDRIA VA

TO THE

SCIENTIFIC MANAGEMENT REVIEW BOARD

OF THE

NATIONAL INSTITUTES OF HEALTH

BETHESDA, MD

APRIL 28, 2009

Chairman Augustine and Members of the Board:

Thank you for the opportunity to present written testimony to you today. We are most grateful for the willingness of the Board to hear from those of us who work in the field and to read the genuine concerns that many of us in the scientific research community have with the path that is being considered here today.

My name is Scott Friedman, MD. I am the Fishberg Professor of Medicine and the Chief of Liver Diseases in the Division of Medicine at Mount Sinai School of Medicine in New York City. In addition, I am the current President of the American Association for the Study of Liver Diseases, based in Alexandria, Virginia and on whose behalf Dr. Szabo and I are submitting this testimony.

My name is Gyongyi Szabo, MD, PhD. I am a Professor and Associate Dean for Clinical and Translational Research, as well as the Director of the Hepatology and Liver Center in the Department of Medicine at the University of Massachusetts Medical School. In addition, I am the Chair of the NIH Liaison Committee of the American Association for the Study of Liver Diseases (AASLD).

**The AASLD is the leading organization in the world representing researchers and clinicians in liver disease and liver wellness. We are unalterably opposed to the SMRB moving forward with the consideration of a merger between the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA).**

Let us be very clear about what we just said. AASLD is not just opposed to merging these two institutes. We are opposed to the SMRB even *considering* the merger of these two institutes and we will explain the scientific implications of such action by this Board – both on research that benefits our patients and on the investigator community – in our statement.

We fully understand that this issue will be addressed by the SMRB in terms of its impact on science and we believe that is appropriate. This should not be about individual research portfolios, nor should it be about bureaucratic convenience. But, underlying all the analysis that must be done is a fundamental fact: **Any action taken by this Board – and by any of us – must be action taken to benefit patients. We don't do research for research's sake – we do it to keep healthy people well and to make sick people better. If consideration of merging these two institutes impairs that mission – and we strongly believe it does – then it should not go forward.**

Liver Disease and the NIH

For the Board to fully understand our position, it is critical that it fully understand the larger picture of the distribution of liver disease-related research throughout the National Institutes of Health (NIH).

According to the Action Plan on Liver Disease Research published by the NIH in December 2004, 18 Institutes, Centers, and Offices currently support and collaborate on liver and biliary disease research. That research portfolio is coordinated by the Liver Disease Subcommittee of the Digestive Diseases Interagency Coordinating Committee (DDICC). Far from being a detriment to liver research, the diversity of scientific opportunities presented by this wide-ranging structure has served to invigorate the science, promote opportunity and competition, and therefore advance the wellness of the public.

**The wide variety of Institutes and Centers addressing liver disease and liver wellness is a strength of the NIH system, not a weakness, and it needs to be recognized as such.**

Consideration of a Merger: The Impact on Science

As the SMRB deliberates the question of whether or not to consider a merger of NIAAA and NIDA, there is no immediate question that is more important than the impact that such consideration will have on science and therefore on health. **It is the position of the AASLD that the impact of such consideration will slow scientific progress in a field that is critically important today and is growing in importance as we speak.**

Please consider the following points relevant to extramural research as you deliberate:

- It is currently estimated that more than 2 million Americans suffer from alcohol-related liver disease. While in 2001 there were 27,035 deaths from alcohol related chronic liver disease and cirrhosis, the impact of alcohol use on liver diseases extends beyond this population. Alcohol use together with hepatitis C virus (HCV) and hepatitis B virus (HBV) infection accounts for 70-90% of all cases of chronic liver diseases in the western world. Up to 44% of individuals with chronic HCV infection has a history of alcohol abuse, and alcohol abuse has been identified as an independent risk factor for liver cirrhosis and development of hepatocellular cancer.

- NIAAA is the primary source of extramural NIH funding for alcohol-related liver research. Although NIDDK's liver research portfolio is six times larger than NIAAA, alcohol-related liver studies are supported only by NIAAA. As a result of this focused effort of research funding and research direction from NIAAA, there have been significant milestones reached in alcohol-related liver research that have directly benefitted patients in the United States and throughout the world.

- NIAAA-supported research has lead to seminal discoveries in liver diseases in general, not limited solely to alcohol-related liver disease. For example, discovery of the concept of liver inflammation as a result of gut-derived pathogens in alcohol-related liver disease was seminal, and impacted the entire field of hepatology by unearthing a critical

pathogenic mechanism common to liver diseases of any origin. In addition, mitochondrial dysfunction, which was first discovered in alcohol-related liver disease research, applies to all kinds of liver disease.

- Similarly, the "multiple hit hypothesis" originally discovered in alcohol-related liver disease, has become the central element of the pathogenesis of non-alcoholic fatty liver disease (NAFLD). NAFLD has a major impact on the society and liver diseases in the United States, and many of the discoveries in NAFLD were made by investigators supported by NIAAA funds.

- In addition, NIAAA-funded alcohol research paved the way to discoveries in obesity and metabolic syndrome research, thus advancing the science in two research fields that are critical to public health.

- Again, as a result of NIAAA supported research, we now know that gut-derived microbes due to either increased gut permeability or impaired detoxification in the liver, contribute to disease progression in NAFLD, HCV and HIV-related liver damage, diseases that afflict millions of Americans.

- Discoveries in alcohol-related liver research directly lead to the progress made in the understanding of NAFLD, the most common liver disease in the US. Pioneering work in signal transduction pathways and nuclear receptors in alcohol-related liver injury tremendously benefited research in NAFLD.

- It has been long known that alcohol use is a cofactor in progression of chronic infection with HCV or HBV. **NIAAA is the only NIH institute that supports research on the combined effects of alcohol with other liver insults.**

In addition to the impact on extramural investigation, it is important that the Board carefully consider the likely deleterious impact on the intramural research program at NIAAA, as well:

- The NIAAA intramural research portfolio supports very high quality liver-related research. Within the intramural component of NIAAA, the research program of four of the 19 principal investigators is focused either exclusively or predominantly on liver biology.

- Breakthrough research on metabolic syndrome has lead to recognition of the role of the liver as both a source and target for endocannabiniods. This lead to a new path in research that has resulted in the founding of a new biotech company to develop compounds that have now been patented. These compounds effectively reduce weight and hepatic steaosis, improve glucose tolerance and dyslipidemias without causing depression or anxiety, a major improvement for patients.

Because the extramural research program in these institutes – and throughout the NIH – tends to be substantially larger and more geographically dispersed, there is a tendency to overlook the important work done intramurally at NIH. But, just these two examples point to the important role played and successes that have occurred under the current structure.

Consideration of the Merger: The Impact on Investigators

Beyond the scientific impact that the deconstruction of the NIAAA alcohol-related liver focus would have, it is important that consideration also be given to the likely impact on the investigator community. Established investigators who are either considering mid-career moves and potential young investigators are likely to be negatively impacted by consideration of merging these two institutes.

Both these classes of investigators take years to develop. The pipeline is a long and laborious one, not a spigot that can be turned on and off and on again. Nothing scares potential scientific researchers from the field they are considering faster than uncertainty. And, the process of undergoing a review by the SMRB is the definition of uncertainty.

By the time the SMRB goes through its public processes and private deliberations, the Director of NIH reviews the recommendation, the Secretary reviews the Director's recommendation, and the issue is referred to Congress for a six month waiting period during which the Congress could prevent its implementation, uncertainty about the future of alcohol-related research will prevail. This could be devastating to the alcohol-related liver research community. Potential investigators could easily decide to look into other aspects of liver disease.

NIDDK's liver research budget is six times larger than NIAAA's. NIAID's is more than twice as large; NCI is also about double that of NIAAA. There are plenty of other opportunities in liver research. But for the two million or more Americans who suffer from alcohol-related liver disease, they do not get to switch to another disease when the researchers are switching to another specialty.

Conclusion

On behalf of the AASLD, we want to thank the SMRB for the opportunity to present our views here today. We very appreciate the difficult and complicated job you have before you and wish to make a positive and constructive contribution to this debate.

To summarize, AASLD believes that to consider merging NIAAA and NIDA will:

- Negatively impact the science of alcohol-related liver research and thus negatively impact on the health and well-being of the public; and,

- Negatively impact the recruitment and training of new researchers in the field.

**We certainly understand the surface appeal of a suggestion to merge these two institutes. But, we believe that a careful analysis of the impact that consideration of such a proposal will have on the science – both today and in the future – belies that superficial appeal. Rather, it clearly demonstrates that the negative impact on the science – <u>and therefore on the public's health and well-being</u> – far outweighs the minor benefit to NIH administrators of having one less institute with which to deal.**

Again, we want to thank you for having the opportunity to present this testimony to you and we welcome the opportunity to participate in this dialogue.

# AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY

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April 22, 2009

Norman R. Augustine, Chair
Scientific Management Review Board
Office of the Director
National Institutes of Health, Building 1
Bethesda, MD 20892

Dear Mr. Augustine,

On behalf of the American Academy of Child and Adolescent Psychiatry (AACAP), thank you for the opportunity to comment on the proposed merger of the National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA).

The AACAP is a medical membership association established by child and adolescent psychiatrists in 1953. Now over 8,000 members strong, the AACAP is the leading national medical association dedicated to treating and improving the quality of life for the estimated 7 – 12 million American children and adolescents under 18 years of age who are affected by emotional, behavioral, and developmental disorders.

Given the tremendous co-occurrence of mental disorders and substance abuse, AACAP is acutely aware of the importance of the prevention and treatment of adolescent substance use disorders. The AACAP Substance Abuse and Addiction Committee includes representatives from our membership who have a special expertise in prevention, treatment, research, and education on co-occurring mental disorders and substance abuse.

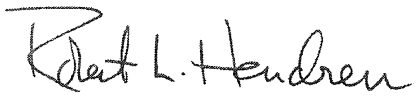
Because alcohol and other substance abuse disorders co-exist with such frequency, the AACAP Substance Abuse and Addiction Committee supports the idea of a collaborative focus on alcohol and substance use disorders. At the same time, the Committee is concerned that a possible merger or restructuring would impact the allocation of resources and funding support of these important public health topics.

The AACAP would like to stress the ongoing importance of and need for research funding across the spectrum of substance use disorders and urge NIH to not lose focus of the overall missions of NIDA and NIAAA if any restructure process is to occur. Should this plan become a reality, the lower levels of a new institute would need to be organized so that they preserve specific areas of basic science as well as specific areas of focus (e.g., underage drinking, prescription drug misuse/dependence, club drugs, nicotine use, etc.). Additionally, because NIDA and NIAAA have both engaged in educational activities at a number of levels, including government administrators, elected officials, general public, school-aged children, and scientists, we would encourage a continued growth of resources available for these initiatives.

The AACAP is dedicated to addressing the problem of substance abuse through early identification and treatment of risk factors, provision of integrated clinical services, promotion of research, and advocacy. In working toward the advancement of this mission, we also propose that any restructuring plan include a more formalized connection with the Substance Abuse and Mental Health Services Administration (SAMHSA). Such collaborations are an important step for child and adolescent psychiatrists when it comes to translating research findings to clinical practice and in disseminating evidence-based practices through professional publications, continuing medical education, and public education.

Thank you again for your time and consideration in this matter. We look forward to maintaining open lines of communication throughout the restructuring consideration process to ensure the current level of support and conduct of research across a full range of disciplines are continued.

Sincerely,



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AACAP President

CC: Alessandra Kazura, M.D., Co-Chair, Substance Abuse and Addiction Committee
Himanshu Upadhyaya, M.B.B.S., Co-Chair, Substance Abuse and Addiction Committee

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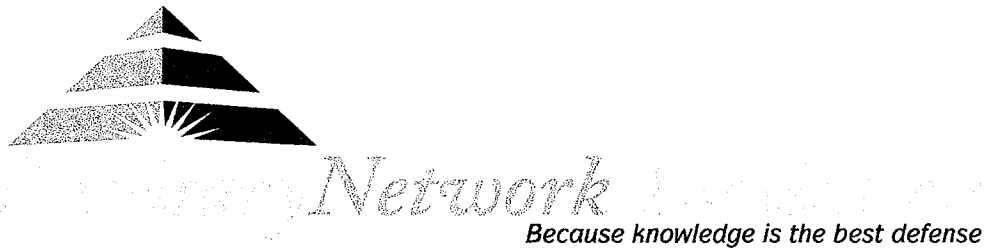


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May 18, 2009

Mr. Norman R. Augustine, Chairman
**Scientific Management Review Board**
C/o Ms. Lyric Jorgenson, Ph.D.
NIH-AAAS Scientific and Technology Policy Fellow
Office of Science Policy
Office of Director, NIH
National Institutes of Health
Building 1 Room 218 MSC 0166
9000 Rockville Pike
Bethesda, MD 20892

Re: National Institute of Hormonal Health and Metabolic Disorders

Dear Mr. Augustine, Board Members and staff:

On behalf of the Pituitary Network Association I wish to express our gratitude for allowing us to appear and make a presentation at your recent Board Meeting on April 27 and 28. We assume that you received our written support materials along with our presentation.

The creation of a "National Institute of Hormonal Health and Metabolic Disorders" has been an ongoing goal of the PNA, supported by our Scientific Advisors, by consultant Physicians and Surgeons, and by Patient Members for the past 12 years.

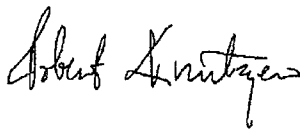
We understand that the Directors and staff of the NIH are concerned about the impact of major change and re-organization. Nevertheless we ask your committee to acknowledge that the Status Quo is unacceptable. It has done a great disservice to past and current patients and to the scientists working in this field. We ask only that up-to-date information be considered to recognize the prevalence and impact of these disorders. Pituitary hormonal medicine only became a reality with the identification of new hormones and therapies in the late 1960's and 1970's; today, diagnostic tools provide accurate assays to detect abnormalities of circulating hormones and we know that small hormonal changes have a profound effect on quality of life as well as longevity. However, the signs and symptoms are subtle and without awareness, these diseases usually smolder undiagnosed for many years, wreaking havoc on patients, their families and society.

Change is difficult but denial can be dangerous." Everything that can be invented has been invented" Charles H. Duell, Commissioner, US Patent Office is reported to have said in 1899. While this quote cannot be authenticated, the following have been: "No one knew better than the US Patent Office Commissioner that the industrial revolution in America was a time of fantastic innovation and change. Still, he wouldn't see the Wright brothers' airplane for four more years, the Model-T for nine years, or the first moving assembly line for fourteen years; nor would he see the radio, television, atomic power, microwaves, computers, or thousands of other inventions. In 1994 alone, 113,268 patents were issued. In 1981, Bill Gates said "640K ought to be enough for anybody"; within three years, the Chairman of Microsoft would realize that because MS-DOS limited users to 640K RAM of hard disk storage, it was becoming obsolete. In response to users' needs, he developed OS/2; released in 1987, OS/2 offered 25,000 times more memory -- 16 megabytes of RAM. Successful change management can lead to greater success.

In the field of medicine we have seen the emergence of HIV and SARS, proving that biology too can and does change its profile with time. We are all familiar with daily news stories reporting abuse of metabolic steroids, the frequency of anger, suicide, and depression, the epidemic of obesity and diabetes, and rising infertility rates. These are all hormonal in origin and society will benefit from a better understanding of their biological basis. The research in Traumatic Brain Injury (TBI) shows that twenty percent of TBI patients in the general medical population have hormonal dysfunction. This data point can be further be extrapolated to identify one fifth of combat Veterans with TBI who may have hormonal dysfunction. It is clear that the US general population as well as our Veterans would benefit immensely from the creation of a National Institute of Hormonal Health and Metabolic Disorders.

We at the PNA respectfully request the SMRB to take action to rectify the situation. We are fortunate to be able to offer the assistance of (Retired) Colonel Wes Weiner, PNA's Director of Military Liaison, who will provide a point of contact in the effort to establish a National Institute of Hormonal Health and Metabolic Disorders (NIHH&MD).

Sincerely,



Robert Knutzen
CEO/ Chairman
Pituitary Network Association

RK; JM

Cc: PNA Board of Directors
PNA Scientific Advisory Panel
Col. Ret. Wes Weiner
PNA Consultant, David Norgard

Encl: Materials

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April 27, 2009

Dr. Lyric Jorgenson, PhD
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Bethesda, MD 20892

Dear Dr. Johnson;

I am writing as a follow-up to the April 27, 2009 meeting of the NCADD Medical-Scientific Committee and NCADD Board of Directors, regarding the April 28, 2009 meeting of the National Institutes of Health (NIH) Scientific Medical Review Board (SMRB).

As we understand it, one of the items on the agenda is a discussion about the possible merger of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA).

Regarding the proposed merger of NIAAA and NIDA, NCADD is concerned about the viability of support for alcohol research and needs more information before taking a position. NCADD must be convinced that any merger would enhance resources to finance the missions of both institutes.

In addition, without a Secretary of DHHS, a Director of NIAAA and a Director of NIH, several key leadership positions that are needed and necessary to effectively guide these discussions are critically absent.

We look forward to hearing an update on the SMRB meeting discussion as well as working together to expand the impact of NIAAA and NIDA.

If you have any questions please feel free to contact me.

Sincerely;

Robert J. Lindsey, M.Ed., CEAP
President/CEO

Name: Peter M. Monti
Address: Brown University
Box G-S121-5
Providence, RI 02912
Telephone No: 401 863-6661

Testimony of Peter M. Monti, Ph. D.
President Research Society on Alcoholism
Academic Title: Distinguished Professor of Alcohol and Addiction Studies, Brown University

President Shapiro, Members of the Scientific Resource Management Board of NIH: I am Dr. Peter Monti, Professor of Medical Science at Brown University, a member of the National Advisory Council for NIAAA, and President of the Research Society on Alcoholism (RSA). The RSA was established in 1976 to serve as a meeting ground for scientists working in all fields of alcoholism and alcohol-related problems. Our society represents over 1,600 scientists who are committed to understanding and intervening in the consequences of alcohol through basic research, clinical protocols and epidemiological studies. The task that you have before you, to recommend whether to consider a merger of NIAAA and NIDA, has been visited by other committees and groups over the past two decades. In my testimony, I hope to convince you of the importance of NIAAA as a distinct Institute focused on the scientific inquiry of the manifold public health consequences of alcohol use.

As a globally unique institution created by the American people, the NIH continues to demonstrate its critical role in advancing human health through scientific discovery and the applications of science to patient care and disease prevention. Before considering major structural changes in a successful organization, it is incumbent on the advocates of change to identify problems that were not addressed because of the present structure, and how proposed changes in the structure would improve performance without creating a new set of problems.

As the premier scientific organization in the alcohol field, RSA believes that there has been no significant mandate of alcohol research that could not be addressed with the present structure of NIH. Further, we believe that a merger of NIAAA with NIDA would impede scientific progress and create serious problems. Prior to the creation of NIAAA, the field of alcohol research had labored in a climate of public denial that alcoholism was even a problem. There was a widespread lack of attention among health professionals to the need for finding ways to treat and prevent alcoholism and alcohol-related illness. NIAAA's emergence as an Institute brought the importance of alcohol problems to national attention. It also signaled to researchers outside the community that alcohol research was an important area of scientific inquiry and thus attracted the best and brightest investigators to the field.

Alcohol and the Public Health: NIAAA is one of the smallest Institutes at NIH addressing

one of the most significant public health problems. Because of its ubiquity in the environment and its contribution to health, disease and public safety risks throughout the life cycle, alcohol research has a very broad scientific agenda. Toxic in high doses and over time, alcohol can have damaging effects on multiple organ systems, including the liver, pancreas, other endocrine organs, the immune system, heart, muscle, and the peripheral, and central nervous systems. Alcohol is also a risk factor for certain cancers. Both directly, and through its effects on nutritional status, alcohol related toxicities account for more than 30% of admissions to hospitals in the US. Excessive drinking contributes to over one-third of automobile-related deaths and is associated with non-motor vehicle trauma, occupational injuries, criminal violence, suicide, family violence, as well as many chronic health problems. Over 1,400 students in American colleges and universities died in alcohol-related unintentional injuries in addition to 500,000 full time four-year university students who were injured while under the influence of alcohol. These are America's future leaders. In aggregate, the cost of alcohol abuse to this country is estimated to be $185 billion, due to lost productivity, health care expenditures, criminal justice system costs and costs related to alcohol related motor vehicle crashes. The public health needs related to alcohol misuse, abuse, and dependence are self-evident, and underline the imperative for preserving NIAAA as an independent Institute at NIH dedicated to research on alcohol-related health problems.

Alcohol is Unique Among Drugs of Abuse:
Alcohol is unique among all drugs of abuse. Non-prescription use of most drugs of abuse is prohibited by law. The use of tobacco, while legal, results in severe injury to multiple organ systems and has no health benefits. Therefore, prevention and cessation of use is the public health goal for all illicit drugs and tobacco. In contrast, alcohol is legal, socially acceptable, and used responsibly by 100 million Americans, to their social and medical betterment. There is convincing evidence that moderate alcohol use reduces the risk of heart disease and stroke. However, some individuals who are unable to limit their drinking experience the protean medical, psychological, and social consequences of alcohol abuse and alcoholism. Research is required to explore both the beneficial aspects of moderate alcohol use and the factors that govern the transition from moderate to harmful drinking. Because alcohol is widely available, heavily advertised, socially sanctioned, and has potential health benefits, understanding the development of alcohol abuse and alcoholism poses special challenges. We believe the strategic planning and funding in support of alcohol research would be diluted and unfocused in a merged institute with a primary focus on addiction.

The implicit and explicit message of the research supported by NIDA (and its Director) must be the prevention of use and abstinence from illicit drug use, while the implicit and explicit message of NIAAA-supported research must be the prevention of alcohol-related problems and harm reduction. This leads to the possibility of competing and unworkable institutional goals within any combined substance abuse institute. Any attempt to bring together NIAAA and NIDA would be disastrous for our national drug control policy and its focused message as well as the critical research into the medical consequences of alcohol toxicity.

The Challenges and Successes of Prevention Research in the Alcohol Field:
Epidemiologists have determined that those who begin drinking before the age of 15 have four times the likelihood of becoming alcoholic at some point in life than do those who begin drinking later. There is a solid scientific basis for prevention of alcohol problems that extends much further than school-based education (the primary prevention strategy for illicit drugs. The challenge of prevention research has been to develop and test effective ways to teach responsible and safe drinking and to inform the general public as well as high risk individuals about the potential for harm associated with heavy drinking in high risk situations These strategies are directed at lowering the risk of harm associated with alcohol. Epidemiological research has suggested the potential of alcohol to lower the risk of heart disease. More prevention research is essential to determine the most effective approaches to assist people in finding the best and safest drinking style for them. NIAAA-funded prevention research highlights the uniqueness of alcohol among drugs of abuse, and the incompatibility of the harm reduction/moderate drinking message with the abstinence message that is tied to illegal use of drugs and the health related consequences of smoking.

NIAAA Sponsored Research and Public Policy
Alcohol is the third leading cause of preventable death in the United States and yet is legally used and enjoyed by over 100 million Americans. Our public policies regarding limiting the harmful effects of alcohol have been greatly impacted by NIAAA supported research. Examples include studies on minimum drinking age, responsible beverage service training, and research on the elimination of wine and spirits retail monopolies. NIAAA sponsored research has helped to inform the policy debate and to evaluate the effects of policy implementation. Research by NIAAA sponsored scientists was used in public discussions in the U.S. Congress in requiring that all states establish at least a .08 BAC limit as well as providing incentives for states to pass “Zero Tolerance” laws for young drivers. A good example of a government-sponsored effort to evaluate all available research on a policy topic was the U.S. Government Accounting Office review of minimum alcohol purchase age research This study, which was commissioned by the U.S. Congress, reviewed all published research, most of which had been supported directly by NIAAA, accounted for their differences in methods and quality, and reached a policy conclusion that there was clear evidence that higher minimum drinking ages yielded reduced alcohol-involved traffic crashes for young people.

The Breadth of NIAAA-Supported Research:
In addition to research related to prevention and public policy (cited above), NIAAA supports all areas of research relevant to alcohol, alcohol-related problems, alcohol-related toxicity, and alcohol abuse and dependence. The following is a very brief summary of some research accomplishments with more detail provided in the appendix to this testimony:
☐**Genetic Research**: Results of epidemiological genetic studies conducted over decades have revealed that about half the risk of alcoholism is genetic. The Collaborative Study on the Genetics of Alcoholism (COGA) has identified several chromosomal regions likely to contain some of these genes and serves as a human reference library for the mechanistic approaches of behavioral genetic studies in animal models.

☐**Neuroscience Research**: Using animal models, including targeting specific genes, investigators have been able to observe the molecular and cellular pathways of alcohol-related behaviors. Recent research has found specific components of nerve cells act as a "front door" access of alcohol into neural function. These findings provide new targets for intervention.

☐**Liver Disease**: NIAAA-funded research has revealed a complex chain of alcohol-induced molecular events that begin in the gut and follow the bloodstream to the liver, where components of the immune system then trigger production of damaging free radicals and inflammation. NIAAA-funded investigations have strong evidence that treatment with antioxidants attenuates this alcohol-induced liver damage.

☐**Fetal Alcohol Syndrome**: Significant progress has been made in understanding the biological mechanisms through which maternal drinking during pregnancy damages the developing nervous system and underlies the leading preventable cause of mental retardation in the Western Hemisphere. This research is the foundation for developing treatments that promote recovery and normal brain function.

☐**Treatment Research**: NIAAA-funded clinical trials has produced two new medication approved by FDA for the treatment of alcoholism, and evaluated dozens of other promising formulations. Additional clinical trials revealed the synergistic effects of brief behavioral intervention with pharmacotherapy in a primary care setting providing a basis for widely-available treatment approaches.

☐**Interdisciplinary Research**: Only an Institute dedicated to alcohol research can focus resources on the multiple causes, consequences, and elements of recovery that define alcohol related problems, toxicities and dependence. These are all influenced by multiple host susceptibility factors (e.g. personality, metabolism, genetic variations in responses to alcohol); by multiple environmental factors that promote or deter excessive alcohol consumption (e.g., availability, peer relationships, religiousness); and by the unique pharmacology of alcohol. It is necessary to support collaborative research designs that span from the molecular to the behavioral and social sciences and provide the knowledge for ever-more efficacious treatment and prevention strategies

☐**Lifespan Research**: Understanding of the environmental, bio-behavioral and genetic factors that promote early initiation of alcohol drinking and transition into harmful use/abuse and dependence (alcoholism), as well as the factors that promote remission and abatement of alcohol problems in untreated populations.

☐**Military** Early drinking has significance for our military as well as our civilian population. Of the 180,000 young adults ages 17-24 who enter the military annually, 75% are drinkers at the time of entry, and of these 28% of males and 13% of females report drinking patterns that are defined as heavy, high risk drinking. Age of drinking initiation and amount of heavy drinking as a teen are directly related to a continuation of drinking while in military service. Heavy drinking in the military poses a vital threat to military preparedness and to the defense of our nation.

☐**Special Populations** Understanding of the interplay of biological factors (genetics, metabolic, age, sex), cultural/ethnic background, and socio-economic status as risk factors for the development of, and the course of, different kinds of health and social problems associated with alcohol use and abuse across the lifespan.

Summary:

In summary, the RSA believes that alcoholism research is poised to capitalize on our past 40 years of NIAAA supported research and change existing paradigms for the prevention and treatment of alcohol-induced disease states and alcohol dependence within the decade. Some of the nation's most vulnerable and venerable sectors (the unborn, victims of childhood trauma, adolescents, college and military) are waiting for these advancements. In the absence of an Institute focused on alcohol and alcoholism, alcohol research will fail to reach this imperative public health goal.

The advocates of change have not identified deficiencies in the present structure and have not shown how proposed changes in the NIH structure would improve performance without creating a new set of problems. In contrast, we believe that a merger of NIAAA with NIDA would damage our national drug control message, while also harming alcohol specific research efforts. If you examine the NIAAA portfolio carefully, you will note that it does not fall within any possible cluster of another Institute's mission statement. In addition, the merger is unnecessary as there are no major barriers to collaborative efforts between NIAAA and NIDA on matters of addiction. However, a merger of NIAAA with NIDA would almost certainly decrease the comprehensive approach to alcohol-related health disorders that includes, but is not limited to, studies of addictive behavior and brain disease. Finally, when NIAAA was part of the ADAMHA cluster, it was never able to attract an active scientific leader to the helm. NIAAA has benefited over the past decades from the leadership of highly distinguished physician-scientists who report directly to the NIH Director and Congress regarding the impact, prevention and treatment of alcohol abuse and alcoholism on our public's health.

Any plan to merge multiple NIH institutes must take into account the costs and benefits. RSA believes that the considerable disruptions associated with any merger are not counterbalanced by the loss of focus on the entire NIAAA portfolio. There is no compelling reason for raising the question of merger at this time. Moreover, in the absence of a Secretary of HHS, a permanent NIH Director, and a permanent Director of NIAAA, the timing of this examination of the organization of NIAAA and NIDA is mystifying and risks damaging NIAAA and discouraging the best candidates from applying for the currently vacant position of NIAAA Director.

Thank you very much for this opportunity to testify before your Committee.

Appendix

NIAAA Research Accomplishments

The Breadth of NIAAA-Supported Research:

NIAAA supports all areas of research relevant to alcohol, alcohol-related problems, alcohol-related toxicity, alcohol abuse and alcohol dependence. The following is a brief summary of some research accomplishments that illustrate the breadth of research funded by the NIAAA.

Genetic Research: Results of epidemiological genetic studies conducted over decades have revealed that about half the risk of alcoholism is genetic. Finding the multiple genes that underlie this risk has been one of the highest priorities of NIAAA. The Collaborative Study on the Genetics of Alcoholism (COGA) has identified several chromosomal regions likely to contain some of these genes. More recently, investigators strengthened these findings by replicating them in two of these chromosomal regions.

Neuroscience Research: In recent years, neuroscience research has increasingly been shaped by research in molecular genetics. Genes that underlie alcoholism produce proteins that regulate the functions of the nervous system. Alcohol interferes with brain function and behavior through its effects on these proteins. With chronic high dose alcohol exposure, the brain undergoes molecular adaptations that result in alcoholism. Much of the research on mechanisms of alcohol dependence relies heavily on animal models, including gene knock-outs or knock-ins, in which a specific gene's activity can be eliminated or enhanced. These models enable investigators to observe the effects of genetic change on alcohol-related behaviors. This research has provided very strong evidence that specific components of specific proteins on nerve cells act as binding sites for alcohol molecules, that components of proteins that regulate appetite for food also probably play a role in propensity for alcohol, and that alcohol disrupts the function of several protein components that act as chemical messages within the nervous system. The latter effects of alcohol disrupt molecular activities crucial to normal nerve-cell function and, thus, brain function and behavior.

Liver Disease: NIAAA-funded research has revealed a complex chain of alcohol-induced molecular events that begin in the gut and follow the bloodstream to the liver, where components of the immune system then trigger production of damaging free radicals and inflammation. NIAAA-funded investigations have strong evidence that treatment with antioxidants attenuates this alcohol-induced liver damage.

Fetal Alcohol Syndrome: Alcohol also damages the developing nervous systems and other organs of unborn children whose mothers drink during pregnancy, often resulting in the life-long deficits of fetal alcohol syndrome (FAS). FAS is the leading cause of preventable mental retardation in the United States. At present, there are no treatments that will prevent the damage of FAS or ameliorate it once it has occurred. However, significant progress has been made in understanding the biological mechanisms through which this damage occurs, laying the foundation for the development of treatments that target specific molecular sites. For example, NIAAA-funded researchers have uncovered the role that alcohol-induced free radicals play in fetal tissue damage, and, in vitro, the ability of antioxidants to neutralize these destructive molecules and attenuate their devastating effects. They have developed a clearer picture of the mechanisms through which alcohol interferes with the normal life-and-death cycles of developing fetal cells and their differentiation into the specialized tissues of the body. They have also shown,

for the first time in a living mammal model, that genetic manipulations that increase production of nerve-growth factor protect a fetal brain region normally sensitive to damage from alcohol. Nerve-growth factor is among the substances that regulate survival of fetal brain cells and their differentiation into specialized cells of the nervous system. Importantly, NIAAA-funded researchers have demonstrated that it is possible to attenuate alcohol-induced damage *after* birth by administering choline, an essential nutrient in humans. Choline is among the substances in the nervous system that enable nerve cells to send electrical and chemical messages to and from each other and their environments, to trigger and regulate crucial biological activities.

Treatment Research:

NIAAA has led the way in the development and testing of promising medications and non-pharmacological treatments of alcoholism. NIAAA-funded clinical trials produced the first new medication approved by FDA for the treatment of alcoholism in more than four decades. The research has demonstrated that, naltrexone is very effective in preventing relapse in some recovering alcoholics. Once neuroscience research provides a more complete picture of how specific protein sites interact with alcohol and how the chronic effects of this interaction can be modified, medications can be developed to alter the pathophysiological mechanisms of alcohol dependence. In the behavioral arena, NIAAA funded Project MATCH which determined that three types of treatment -- cognitive-behavioral, motivational enhancement, and 12-step programs -- are equally effective in treating alcoholism and Project COMBINE which studied combinations of behavioral therapies with pharmacotherapies. Investigators continue to study which of many treatment modalities are most cost-effective.

Prevention Research: Prevention research supported by NIAAA over the past 20 years has established the basis for science-based prevention programs and approaches for every U.S. community and state. In addition to its contribution to public policy concerning BAC limits for youth and the underage drinking laws, recent advances in NIAAA prevention research include a series of community prevention trials which have shown significant effectiveness in reducing underage drinking initiation as well as drinking levels (Project Northland and Communities Mobilizing for Change on Alcohol) and alcohol-involved trauma (Community Trials in California and South Carolina). NIAAA sponsored research is currently undertaking extensive prevention effectiveness trials of comprehensive campus and community interventions to reduce college student high risk drinking and associated injury and death.

# National Association of Addiction Treatment Providers View on the proposed merger of NIAAA and NIDA

In broad business terms, it is always appropriate to examine whether or not the consolidation of organizations will achieve cost savings, efficiencies and a structure which can respond to the changing environment in ways that the former entities could not. To consider such options in the case of **NIAAA (National Institute on Alcohol Abuse and Alcoholism)** and **NIDA (National Institute on Drug Abuse)** is certainly appropriate, it is just not advisable!

Within the political and public policy climate, it has been fashionable for our country to focus on the impact of drugs (legal and illegal) within our society. This has occurred at the expense of focus on and attention to alcohol which remains the number one problematic drug in our society. Witness the continued disturbing "split" within the **Office of National Drug Control Policy** where the charter of this organization makes it impossible to address or to craft a policy which incorporates alcohol into a national drug control policy.

The fact that we have two separate institutes under **NIH** may be an administrative challenge, but it nevertheless serves as a firewall against the complete ignoring of alcohol as the number one drug in this country. The National Association of Addiction Treatment Providers believes that we need to hold true to the principles espoused by Senator Harold E. Hughes who was the moving force behind the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (Public Law 91-616) which established NIAAA. Recognition of Alcohol as a drug and of the outrageous effects of the disease known as alcoholism has served us well! To diminish this impact, to lessen this recognition will not serve us well in the years ahead.

In the early years, NIAAA was an Institute with whom the providers of addiction treatment felt comfortable worked with and supported. Over the past decade, that relationship has become strained and to some extent fractured. Less and less emphasis has been placed on researching the impact of the disease of alcoholism on our society and on researching the impact of treatment and examining treatment efficacy. More emphasis has shifted to researching alcohol and its impact on the body and attempting to build an understanding of "problem drinkers" as opposed to embracing the understanding of alcoholism as a primary disease.

At the same time the overall budget for NIDA has grown to the point where it is approximately 57% larger than the annual budget for NIAAA. Any merger of these two institutes would ultimately result in reduced resources being allocated to alcoholism which are already receiving less then their fair share.

Because of the issues raise above, the National Association of Addiction Treatment Providers opposes a consolidation of NIAAA and NIDA. NAATP believes that both institutes have a unique mission which needs to be protected and expanded. Instead of a merger, we urge NIH to commit itself to returning to some of the original principles which led to the creation of both NIAAA and NIDA and to reconnect itself to its partners on the treatment side, especially in the private sector and again establish itself as a leading voice for understanding addiction as a primary disease and for promoting treatment which goes well beyond the reduction of heavy drinking days per month, but which promotes long term recovery. We believe that this is best accomplished through maintaining two separate institutes; NIAAA and NIDA.

National Association of Addiction Treatment Providers
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Lancaster, PA 17602
Ronald J. Hunsicker, D. Min., FACATA, President/CEO rhunsicker@naatp.org

DATE: April 27, 2009

TO: Lyric Jorgenson, Ph.D., NIH-AAAS Science & Technology Policy Fellow
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CC: Mr. Norman R. Augustine, Chair, Scientific Management Review Board

RE: Scientific Management Review Board meeting April 27-28
*Please continue NIAAA and NIDA as independent, unique NIH institutes*

Dear Dr. Jorgenson,

As directed in the March 25, 2009 Federal Register, I am sending this letter to you as the contact for comments regarding agenda items for the Scientific Management Review Board (SMRB) meeting April 27-28, 2009. I understand the agenda proposes that SMRB examine issues related to establishing or abolishing national research institutes; reorganizing 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 reorganizing 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. *I am specifically concerned about consideration being given to merging the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and National Institute on Drug Abuse (NIDA).* My comment requests that NIAAA and NIDA remain as independent, unique NIH institutes.

After 25+ years in the field and as a researcher and clinician, I am concerned about this potential merger and the threat it poses to current and future science, policy, and practice research initiatives related to the mission of NIAAA. From both a research and clinical standpoint, I remain impressed with the unique and broad impact of alcohol on public health arena, much more so than any other drug. Alcohol has many facets which, when combined, make it distinct. It is a legal drug and one of the two most expensive drugs to public health (nicotine being the other). It is also the most widely used legal drug subject to consideration for substance-related disorders, after caffeine, and represents a common drug across co-occurring disorders to a greater degree than all other drugs subject to consideration for substance-related disorders. I also think that it raises more interesting questions because so many people use it, volume per dose, *without problems.* Also, beyond prescription drugs, it is one of the few drugs recommended by the government for health purposes to *normal healthy asymptomatic persons* despite its association to dependence and abuse. Historically it also has helped keep a variety of problem

definitions, theories regarding etiology, treatment goal definitions, and treatments on the table for consideration for other substances and behaviors with addictive features.

Unfortunately, the unique perspectives alcohol studies have cultivated are likely to wither if there were to be one super agency oriented toward a unitary concept of addiction that minimizes normal use. And from a public health perspective, this is not a good idea. We cannot leave use in the dust; it is just as important as physiological dependence – and most importantly may be a lot less unitary in nature, as well as more prevalent as a public health concern. Looking for common models across substance is but one perspective in science; recognizing uniqueness also is important - and alcohol is the standout in that regard when it comes to substances. Having one agency stirs fear we will forget the unique aspects of alcohol, especially socio-cultural, and get further inculcated into a biomedical model, which may in fact take us further away from the broader public health issues related to substance use in our culture and perhaps worldwide.

While I understand that fiscal concerns may be operating to drive consideration of a merger at this time, I am also concerned that the timing of this could not be poorer due to a lack in permanent leadership for negotiating issues related to this proposed change. There currently is not a permanent director for NIAAA. This creates a power imbalance between the two agencies being merged that does not favor the mission of NIAAA being preserved or advanced as strongly as it might otherwise be with a permanent director. NIH also not having a permanent director makes this seem even more precarious.

In sum, I urge you to forgo study of a merger between the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism. Doing so would preserve the unique perspective offered by alcohol studies to public health. If continued study on this matter is required however, I urge you to wait until more permanent leadership is available for both NIAAA and NIH so as to facilitate a fairer examination of the potential risks and benefits of a merger.

Thank you for your consideration of these comments. Please note: comments made here are mine and not intended to represent any of the institutions or organizations with which I am affiliated. The affiliations are provided only because they were specifically requested to accompany any comments submitted.

Most sincerely,

Nancy A. Piotrowski, Ph.D.

Core Faculty, Harold Abel School of Psychology, Capella University
Teacher, University of California, Berkeley, Alcohol and Drug Certificate Program
Past President, Division 50 (Addictions), American Psychological Association
Board Member, San Francisco Psychological Association

3450 Geary Boulevard, Suite #107
San Francisco, CA 94118

From: jean public [jeanpublic@yahoo.com]
Sent: Tuesday, March 31, 2009 11:38 AM
To: smrb; INFO@TAXPAYER.NET; MEDIA@CAGW.ORG
Subject: PUBLIC COMMENT ON FEDERAL REGISTER

TY THE WAY THE PRESIDENT HAS CHANGED AND SO HAS THE FOCUS OF WHAT OUR AGENCIES SHOULD BE DOING. PLEASE THROW AWAY WHAT BUSH PUT IN PLACE SINCE HE WAS THE MOST INCOMPWETENT PRESIDENT THIS NATION HAS EVER HAD AND HE WAS ROUNDLY REPUDIATED BY THE MAJORITY OF THE AMERICAN PUBLIC. WHAT YOU DID UYNDER BUSH WENT IN EXACTLY THE WRONG DIRECTION SINCE HE WORKED FOR HIS RICH CORPORATE BUDDIES WHO DONATED CAMPAIGN CASH TO HIM. HE WAS A HORRIBLE PRESIDENT FOR THE PEOPLE OF THIS COUNTRY. IF YOU ARE WORKING FOR THE 2007 PRESIDENT, THE PLAN IS WRONG, COMPLETELY WRONG.

science has been for sale. BIG PHARMA AND BIG MEDICINE HAS BEEN NEGATIVELY IMPACTING THE PUBLIC WITH THEIR FAKE CLINICAL TRIALS DONE IN THIRD WORLD COUNTRIES,K THE CLAIMED BUYING OF MEDICAL DOCTORS EVEN AT HARVARD (DR. BIEDERMIER), THE FAKE CLINICAL REPORTS TURNED IN TO NIH.

IT IS SIMTE THAT THIS AREA GETS CLEANED UP AND THE MONEY FROM BIG PHARMA TO BIG MEDICINE TO BUY THEM STOPS. THE HEALTH OF THIS COUNTRY IS TURNING INTO THIRD WORLD STATUS DUE TO THE BRIBERY AND GREED, WHICH RESEMBLES THE WAY THE SEC REGULATED WALL STREET - THIS SITUATIO NIS JUST AS BAD. IT IS UGLY. IT NEEDS CLEAN UP. IT IS DIRTY, SKANKY AND CORRUPT. NIH IS PRODUCING VBIRTUALLY NOTHING THAT TRULY HELPS AMERICA. THE EMPLOYEES LIKE TO FLY ON CONFERENCES ALL OVER THE WORLD, SPENDING TAX DOLLARS ON HOTEL, MEALS AND TRAVEL, WHEN THEY CAN GO TO THESE CONFERENCES BY SOFTWARE. THE ESXPENDITURE AND WASTEFULNEWSS OF THIS AGENCY IS LIKE WALL STREET. PLEASE CLEAN UP THIS SKANKY MESS AT NIH.
B SACHAU 15 ELM ST FLORHAM PARK NJ 07932

--- On Tue, 3/31/09, jean public <jeanpublic@yahoo.com> wrote:

> From: jean public <jeanpublic@yahoo.com>
> Subject: science has been for sale
> To: jeanpublic@yahoo.com
> Date: Tuesday, March 31, 2009, 7:56 AM [Federal Register: March 31,

> 2009 (Volume 74, Number 60)]
> [Notices]
> [Page 14574]
> From the Federal Register Online via GPO Access [wais.access.gpo.gov]
> [DOCID:fr31mr09-85]
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> DEPARTMENT OF HEALTH AND HUMAN SERVICES
>
> National Institutes of Health
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> Office of the Director, National Institutes of Health; Notice of
> Meeting
>
>  Pursuant to section 10(a) of the Federal Advisory Committee Act,
> as amended (5 U.S.C. App.), notice is hereby given of a meeting of the
> Scientific Management Review Board.
>  The NIH Reform Act of 2006 (Pub. L. 109-482) provides
> organizational authorities to HHS and NIH 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 purpose of the Scientific Management Review Board (also referred
> to as SMRB or Board) is to advise appropriate HHS and NIH officials on
> the use of these organizational authorities and identify the reasons
> underlying the recommendations.
>  The meeting will be open to the public, with attendance limited to
> space available. Individuals who plan to attend and need special
> assistance, such as sign language interpretation or other reasonable
> accommodations, should notify the Contact Person listed below in
> advance of the meeting.
>
>  Name of Committee: Scientific Management Review Board.
>  Date: April 27-28, 2009.
>  Open: April 27, 2009, 8:30 a.m. to 5:30 p.m.
>  Agenda: Presentation and discussion will include an overview of
> NIH mission, structure, budget, perspectives on how science has shaped
> the NIH organization, and future directions. There will also be time
> allotted on the agenda for public comment. Sign up for public comment

> will begin at approximately 8 a.m. on both April 27 and 28. In the
> event that time does not allow for all those
>
> interested to present oral comments, anyone may file written comments
> using the address below.
>  Place: National Institutes of Health, Building 31, 6th Floor,
> Conference Room 6, 31 Center Drive, Bethesda, MD 20892.
>  Open: April 28, 2009, 8:30 a.m. to 3:30 p.m.
>  Agenda: Continuation of April 27th meeting.
>  Place: National Institutes of Health, Building 31, 6th Floor,
> Conference Room 6, 31 Center Drive, Bethesda, MD 20892.
>  Contact Person: Dr. Lyric Jorgenson, PhD, NIH-AAAS Science and
> Technology Policy Fellow, Office of Science Policy, Office of the
> Director, NIH, National Institutes of Health, Building 1 Room 218 MSC
> 0166, 9000 Rockville Pike, Bethesda, MD 20892.
> smrb@mail.nih.gov. (301) 496-6837.
>
>  Any interested person may file written comments with the committee
> by forwarding the statement to the Contact Person listed on this
> notice. The statement should include the name, address, telephone
> number and when applicable, the business or professional affiliation
> of the interested person.
>  The meeting will also be Web cast. The draft meeting agenda and
> other information about the SMRB, including information about access
> to the Web cast, will be available at http://smrb.od.nih.gov.
>  In the interest of security, NIH has instituted stringent
> procedures for entrance onto the NIH campus. All visitor vehicles,
> including taxicabs, hotel, and airport shuttles will be inspected
> before being allowed on campus. Visitors will be asked to show one
> form of identification (for example, a government-issued photo ID,
> driver's license, or passport) and to state the purpose of their
> visit.
>
>  Dated: March 25, 2009.
> Jennifer Spaeth,
> Director, Office of Federal Advisory Committee Policy.
> [FR Doc. E9-7200 Filed 3-30-09; 8:45 am]
>
> BILLING CODE 4140-01-P