Enoch Gordis M.D.
Former Director, NIAAA
Presentation to the Substance Use, Abuse and Addiction Working Group
Dec 22 2009

Mr Chairman, and members of the committee. Thank you for the opportunity to speak with you today on the proposed merger of NIAAA and NIDA. My perspective on this is shaped not only by my experience as NIAAA director for 15 years, but also by my prior years as both a laboratory researcher and then as founder and director of a large alcoholism treatment program, which served 15000 alcoholic patients during my tenure. I was an active member of the research community, but I also had much interaction with state and local government, community organizations, with treatment professionals and counsellors, as well as with Alcoholics Anonymous.

I will address two main issues: first, the uniqueness of NIAAA's vast scientific enterprise, and the long-standing reasons why this proposed merger would be a tremendous setback to public health.

My first main issue is the uniqueness of NIAAA science. Alcohol is unique both in the scale of its problems, and in the details of alcohol action. The statement regarding both institutes that "the science is the same", which comes so trippingly off the tongue, is a serious misrepresentation of the scientific reality, and results from a very narrow perspective of the universe in which alcohol issues, problems and science play out. Alcohol abuse and alcoholism cost more and kill more than all the illegal drugs together. 80000 deaths a year from alcohol, and an annual bill to society of 235 billion dollars. Much of this cost is attributable not only to alcoholics, that is alcohol dependent people who are addicted to alcohol, but to alcohol abusers who are not addicted but who drink excessively often enough to become ill themselves or to hurt others. NIAAA's mission goes far beyond addiction. This committee has heard before the staggering list of alcohol-related problems, so I will only restate some of them briefly: alcoholic liver disease including cirrhosis, neurological disease including dementia and peripheral neuropathy; pancreatitis; cardiac arrhythmias, alcoholic cardiomyopathy and hypertension; fetal alcohol syndrome and partial fetal alcohol syndrome; increased risk for suicide; trauma, including alcohol related auto accidents---13000 in the year 2006;

interpersonal violence, including fights, sexual assaults which figure prominently on college campuses; alcohol poisoning and toxic interactions with medications. The problem of alcohol abuse is especially great in the military.

The majority of alcohol abusers and alcoholics are not drug abusers. To repeat: the majority of alcohol abusers and alcoholics are not drug abusers. Of the 18 million adults with an alcohol use disorder, only 13 percent of them have a drug abuse disorder as well. Originally NIDA, now with SAMSHA, had a data base called DAWN---drug abuse warning network, which tabulated emergency room visits for drugs and for drugs combined with alcohol. When I once inquired why there was no category for alcohol alone, I was told that that would have "swamped the system". I want to be clear that I am in no way minimizing the tremendous problem of drug abuse: in fact I was privileged to be a member of Dr Vincent Dole's laboratory at the Rockefeller University in the exciting early 1960's when he and colleagues discovered the methadone maintenance method of treatment for heroin abuse, which 45 years later is still the single most effective treatment for any addiction. My interest in and concern about that problem remain.

Alcohol is unique, and the science supported by NIAAA reflects both alcohols unique properties and its extensive toxicity. Alcohol has remarkable properties: it is a metabolized substance, taken by mouth, a source of calories, quite inefficient as a psychoactive substance compared to other drugs, since it must be taken in gram amounts, not milligrams, to have an effect. NIAAA research has shown that alcohol interacts with many receptor systems, both in the brain and outside: gaba,serotonin, acetylcholine, dopamine, glutamate, NPY, cannabinoids, CCK, ghrelin and so on.

NIAAA has pioneered major advances in genetics, organ toxicity and clinical research. Alcohol dependence is highly heritable, and over the last 20 years, in a continuing large human study of alcoholism-dense families, several chromosomal areas have been found with genes very related to alcohol dependence. These findings have been verified in independent analyses by a consortium of international investigators. In general, the evidence shows that a family history of alcoholism is not predictive of drug abuse. NIAAA's portfolio has extensive work on all the alcohol medical complications mentioned previously. The effect of alcohol on one organ can affect function

in another, leading to the institute's emphasis on studying alcohol effects from a system's viewpoint.

NIAAA has supported important work in various mechanisms of hepatotoxicity, pancreatitis, endocrine problems, cardiomyopathy, brain damage, and of course the fetal alcohol syndrome. Alcohol is different in that much of the damage it causes arises from its metabolism and the formation of reactive oxygen species. In recent years, the effect of alcohol on epigenetics has been of great interest; for example, alcohol interferes with essential histone methylation. NIAAA researchers are studying the effects of alcohol on micro RNA control of gene expression in brain and liver. NIAAA supports widespread research in animal models both of drinking itself, and of the organ damage that alcohol produces.

NIAAA was created to solve the problems caused by alcohol. But as a responsible scientific agency, NIAAAA has also supported research on the benefits of moderate drinking, among them, decreased risk of coronary artery disease, ischemic stroke, and osteoporosis.

A major agenda for NIAAA has been rigorous large randomized clinical trials of existing therapies, both verbal and pharmacologic, including traditional approaches like Alcoholics Anonymous as well as newer ones such as cognitive-behavioral therapy, but also medications like naltrexone and acamprosate, which are approved by the FDA to treat alcoholism---an approval based substantially on NIAAA supported research. NIAAA's support for rigorous clinical research has led to the trial of many other drugs for alcoholism and in the last few years the pharmaceutical industry has become attracted to the search for new alcoholism medications. I cannot see where any of the research I have listed would benefit from a merger with NIDA.

Some of the dopamine-based reward circuits in the brain, which function normally to reward eating and sex, are involved both with alcohol and drugs. This commonality of certain neural circuits is hardly justification for merging two very different institutes. There is hardly any pair of NIH institutes where some scientific commonalities aren't found. Examples abound: for instance, the auditory cortex and visual cortex are part of the nervous system, have very similar synapses and receptors, but NIH, for very good reasons, has separate

institutes on vision and hearing distinct from the neurology institute. NIDA's interest in prevention and treatment of intravenous drug abuse is hardly independent of the NIAID's efforts to prevent and treat AIDS.

My second main issue is why I strongly believe that a merger of the two institutes would be a tremendous setback to public health.

Institutes don't arise in a vacuum: they arise each in their own special world of social attitudes and problems, neglected health and research needs, special populations, laws and regulations, and economics. On these matters, NIAAA and NIDA are radically different. NIAAA was created in the early 1970's largely through the efforts of Senator Harold Hughes, himself a recovered alcoholic and others. Hughes believed that this immense problem, much neglected by the public, (and to a large degree by NIMH where alcohol research had been housed), needed a highly visible agency with a unique focus. I might mention that Bill Wilson, the principal founder of AA, where anonymity is a guiding principle, broke his anonymity at that time in order to testify to congress on behalf of establishing the NIAAA.

Alcohol is a legal drug, used safely by most drinkers. It is sold, advertised, taxed, and incorporated in our culture in many ways. This is a very different world than NIDA's. NIDA deals mostly with illegal drugs, and the social milieu involves a large amount of criminal activity, law enforcement, courts, jail, international cartels and tremendous stigmatization of the drug addict by society. Drugs sales are not regulated or taxed, and drugs are not advertised on billboards and television. There are no legal drug outlets throughout communities.

So it should be no surprise that NIAAA's research on prevention and social policy is very different from NIDA. Topics which NIAAA supports in these areas include the impact of price changes on beverage use—a concept called elasticity (a politically sensitive since it involves taxation), the impact of advertising on young people's drinking, the effect of zoning restriction, that is, the effect of controlling the density of alcohol outlets on alcohol problems in a community, effects of enforcement of age restrictions on purchase of alcohol by young people, enforcement of host liability for consequences of serving alcohol to minors, the utility of driving interlocks and so on. NIAAA is very

proud of the fact that its research on the 21 year age limit on driving deaths and injuries was instrumental in the Supreme Court's decision to support the federal government when the federal government pressured the states to enact restrictions on drinking below the age of 21. The 21 year age limit has saved several thousand lives on the highways.

Progess in solving the problems of alcohol faces two main obstacles and such progress depends on NIAAA maintaining its independence, focus and visibility. The first obstacle is the reluctance, despite evidence assembled by now over many years, of the old line treatment community to accept new medical therapies for alcoholism. This reluctance stems from the failure of some older treatment programs to remember the views of Bill Wilson, the far-sighted founder of AA, in his memorable address to the New York Medical Society: his respect for science, and even for potential new treatments outside of AA's approach. The situation is changing now because of the visibility of NIAAA as the leader in bringing science to the clinical area, the attraction of evidence based practice to younger clinicians, and the long-standing mutual respect and friendship between Alcoholics Anonymous and NIAAA. A merger would weaken this important and visible effort. Alcohol would be further stigmatized like illegal drugs, and the pharmaceutical companies, having finally become interested in developing new drugs for alcoholism because of NIAAA research, would abandon their commitment.

But the second and bigger obstacle to progress is our whole country's inability to come to grips with the alcohol issue. As I mentioned, much, if not most damage from alcohol is not only the dependent, that is addicted person or alcoholic, but the high-risk non-dependent drinker, and that's a lot of people. The size of he problem is one feature that makes alcohol issues unique. The alcohol problem and its cost is like the "elephant in the living room": its big, its there, you sort of see it, but after a while you just walk by it. In the drug world there were years of a highly publicized federal "war on drugs", an Office of National Drug Control Policy" was established and continues, but no such focus was developed for alcohol, the far bigger problem, nor would anyone want a war on alcohol----what is missing is national science-based alcohol policy to reduce its misuse. The kind of policy related research I mentioned before, such as research on price, age restrictions, outlet density, and advertising is central to informing the public and their elected representatives

firmly and consistently about the alcohol problem. But a merger will bury these issues in the face of the country's continued preoccupation with drug abuse, to the great detriment to public health. And young scientists, who responded to the need for alcohol research and were attracted by the visibility of NIAAA, will now wonder if alcohol research has a serious home and whether they should make a career of it.

To conclude, this merger proposal will not improve the productivity of either institute and is a setback to public health. Alcohol is a unique substance: unique in its mode of action, in its metabolism, in its widespread damage to the organ systems and to society, and in its legal and regulatory world. Science and public health, both need the NIAAA's independence, visibility and focus. Where there are common interests, of course collaboration should be increased---with NIDA, as well as the other institutes with which NIAAA collaborates.
There are several easily instituted mechanisms that could be introduced to increase collaboration without a destructive reorganization.

Dr Collins has listed global health as one of his priorities. In January 2010, the World Health Organization (WHO) will be releasing its document called "Global Strategy on Reducing the Damage from Alcohol Abuse." Alcohol is the fifth leading cause of premature death and disability worldwide, according to the WHO. This is clearly not a time to bury the NIAAA. That would be a terrible message to the American public and to the global community. There is an old medical maxim: primum non nocere--first do no harm. At a time when the whole world will once again be hearing about the extent of the problems caused by alcohol, I ask this committee and the NIH: please don't take the sign off the door.

Thank you for hearing me out.

March 9, 2010

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

Dear Review Board Chair and Members of the Subcommittee:

As a former clinician and long time educator in the field of substance use disorders, I am writing this letter from a different perspective than you might have heard in expressing my strong support for a merger of NIAAA and NIDA. A perspective from public reaction, perception and public trust.

I have worked in this field for 25 years, first as a clinician and grant writer and then as an educator to many different audiences. Since 1995, when I started teaching and training on the neuroscience of addiction, I have taught one hour, one day, one week and one semester classes to a myriad of groups including: doctors, nurses, mental health professionals, college students, parents, substance abuse counselors, child welfare workers, law enforcement personnel, policy makers, school personnel and people in recovery to name a few. I feel I have a pulse on the public at large from around the country.

The basis of all my talks, lectures and workshops is to convince people from a scientific perspective that *substance abuse* (to alcohol and other drugs) is a preventable behavior and that *addiction* (to alcohol and other drugs) is a brain disease that is treatable. While this makes completely logical sense to my audiences, I am inevitably asked the question of why then are there two separate federal institutions working on this. I have no satisfactory answer for them from a scientific perspective. It simply makes no logical sense – to the public at large or to myself.

While arguments abound in the scientific communities as to whether alcohol is too unique to merge the institutions, the simple fact is that to the public it appears to lesson the credibility of how research is done creating the perception I've heard for many years: "so it's more about the politics than the science." This is tragic because both institutions conduct important work that benefits humanity in countless ways but only if it is seen by the people these institutions serve as working for the good of the public's health not the good of the institution.

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21 N. Park Street, 7th Floor Madison, Wisconsin 53715-1218
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Lastly, while I agree with those who have expressed concern over the enormity of the task involved in a merger, I also know (having been a part of a large merger within our own institution) that if done with integrity and a well thought out strategic plan the results can be beneficial for everyone.

I strongly feel that by not merging these two institutions while discovering more and more about the science of addiction as a brain disease we are not serving our nation's best interest.

Sincerely,

Flo Hilliard, MSH
Faculty Associate
University of Wisconsin-Madison
Division of Continuing Studies
fhilliar@wisc.edu

NADCP
National Association of
Drug Court Professionals

4900 Seminary Road, Suite 320
Alexandria, VA 22311
Phone:703.575.9400
Fax:703.575.9402
www.nadcp.org

March 10, 2010

Norman Augustine, MS
Chair
Scientific Management Review Board,
Working Group Deliberating Organizational Change
Working Group Substance Use, Abuse and Addiction
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dear Mr. Augustine:

The National Association of Drug Court Professionals (NADCP) strongly supports the merger of the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Addiction (NIAAA).

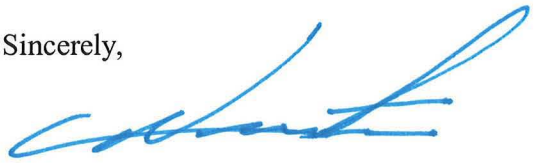
It takes science, innovation, teamwork and strong judicial leadership to achieve success addressing drug abusing offenders in a community. That's why since 1994 the National Association of Drug Court Professionals (NADCP) has worked tirelessly at the national, state and local level to create and enhance Drug Courts, which rely on the science-based and research-based practices to implement a combination of accountability and treatment to compel and support drug abusing offenders to change their lives.

Now a national movement, Drug Courts are the shining example of what works in the justice system. Today, there are over 2,400 Drug Courts operating in the U.S., and another thirteen countries have implemented the model. Drug Courts are widely applied to adult criminal cases, juvenile delinquency and truancy cases, and family court cases involving parents at risk of losing custody of their children due to drug abuse. Drug Court rely on the science to get offenders off drugs, stop drug-related crime, reunite broken families, intervene with juveniles before they embark on a debilitating life of addiction and crime, and reduce impaired driving.

Our rationale for supporting the merger is based on our reality. Drug Courts serve over 120,000 offenders ever year. These offenders have long histories of abusing both licit and illicit substances. In the criminal justice system offenders do not separate their dependency based on what is legal or illegal. Thus, our treatment and accountability approach must integrate both.

On behalf of over 27,000 Drug Court professional around the country working on the front lines, serving individuals every day with both licit and illicit substance abuse problems, NADCP strongly supports the merger of NIDA and NIAAA. We all greatly benefit from integrated research on both the effects of licit and illicit drugs on the brain and effective approaches in accountability and treatment. Merging NIDA and NIAAA has the potential to achieve significant advances in this arena and to inform both policy and practice at the federal, state, and local level as we work to reduce the demand for drugs and the crime associated with it.

Sincerely,



West Huddleston
Chief Executive Officer

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

February 23, 2010

Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
1 Center Drive, Room 126
Bethesda, MD 20892

Dear Dr. Collins:

We appreciate your solicitation of ONDCP input into the potential merger of the National Institutes of Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse. We support this merger, for the following reasons.

First, the nature of American substance use patterns and treatment services suggest that there may be some public health gains from combining NIDA and NIAAA. If one accepts the premise that science on diseases should in some way parallel the way diseases are experienced in the population, it is logical to combine drug and alcohol research. The 2008 National Survey on Drug Use and Health found that two-thirds of heavy drinking teenagers also use illegal drugs. This was not the case when NIAAA was founded in 1970. Similarly, the 2007 Treatment Episode Data Set showed that only 22.7% of people who seek treatment in the public sector are "pure alcoholics"; combined abuse is now the norm and not the exception as it was in prior eras. Studying alcohol and drugs within the same institute would set up a scientific support structure that parallels how these problems are now experienced in American society.

Second, an important goal of the federal science effort is to develop knowledge that can be translated into improved health care services. It is therefore worth noting that the federal government successfully merged funding for alcohol and drug services within the Center for Substance Abuse Treatment (CSAT) over 15 years ago. Alcohol and drug treatment services were merged by most states twenty years ago. In attempting to improve services using science, CSAT and State-level administrators face the challenge of trying to improve an integrated care system based on scattered and sometimes redundant scientific literatures on alcohol versus drugs supported by two distinct NIH institutes. A merged NIDA-NIAAA institute would help resolve this knowledge translation problem.

Third, although alcohol is often perceived as different from other drugs because it can be legally consumed by adults, this is irrelevant from the point of view of the scientific quest to understand the process by which people become addicted to a substance. Given that the mechanisms underlying the reinforcing properties of alcohol are similar to those of illicit drugs (as well as to other widely abused legal drugs, such as prescription pain medication), there should be a significant scientific advantage to studying these two substances in one institute.

While supportive of this merger, we would note a few cautions to be considered if indeed this goes forward. If the institutes are merged and the combined institute is re-conceptualized as dealing only with addictions, there are two risks. First, the public health and public safety impact of substance use among the non-addicted population may get short shrift in the research the combined institute supports. Second, the combined institute may suffer "mission creep" if it is pressed to cover research on all behaviors which are sometimes categorized as addictions, including overeating, gambling, excessive shopping, compulsive collecting and hording etc.. We believe that a merged institute should maintain a primary focus on addictive substances, including of course an ongoing program of research on alcohol proportional to its sizable public health impact. These two concerns do not lessen our support of this merger, but we hope they will be considered during and after any merger.

In closing, we would note that NIDA is currently included in the President's National Drug Control Budget. This implies that a merger of the institutes will require a review by your staff and ours of how to account for what activities of the new agency support the National Drug Control Strategy and therefore would be included in ONDCP's annual budget review process.

Thank you for allowing us to express our support for the proposed merger of NIAAA and NIDA. Please contact us if you would like to discuss this matter further.

Sincerely,

R. Gil Kerlikowske
Director, ONDCP

A. Thomas McLellan, Ph.D.
Deputy Director, ONDCP

cc:
Norman Augustine
Chair, Scientific Management Review Board
6801 Rockledge Drive
Bethesda, Maryland 20817

William Roper, M.D.
Chair of the Substance Use, Abuse, and Addiction Working Group of the SMRB
The University of North Carolina at Chapel Hill
4030 Bondurant Hall
Campus Box #7000
Chapel Hill, North Carolina 27599

Thoughts on a Potential Merger of National Institute on Drug Abuse (NIDA) and National Institute on Alcoholism and Alcohol Abuse (NIAAA)

Alan I. Leshner, Ph.D.
Chief Executive Officer
American Association for the Advancement of Science (AAAS)[1]
Former Director, NIDA

The possibility of merging NIDA and NIAAA has been discussed for at least a decade. In fact, the two Institutes originally were both included within the National Institute of Mental Health, and thus, functionally were a single entity. The current discussion has been ongoing for at least a decade; it has been discussed more publicly since the 2003 National Research Council/Institute of Medicine report on the organization of the National Institutes of Health (NIH) which included the potential merger in one of its recommendations. I have been an active proponent of merging the two Institutes since I left NIH, although I have been discussing it more informally for many years.

The fundamental justification for merging the Institutes is scientific. Although it is true that every drug of abuse has its own idiosyncratic characteristics, including some mechanisms of action and behavioral manifestations, they also all share many neurobiological and behavioral traits and mechanisms of action. Their behavioral manifestations are quite similar, and many scientists believe there is some common neurobiological "essence" of addiction. Moreover, many of the most effective treatment approaches work equally well with all chemical addictions. Therefore, it is straightforward to argue that all substances of abuse should be overseen by a single NIH Institute, or at least that some other mechanism will be forthcoming to ensure that the research is much better integrated across them. In the same way that NIDA has broad responsibility for many drugs of abuse – and in the same way that inclusiveness has benefited studying commonalities among them – merging research oversight of alcohol with other drugs of abuse would benefit that kind of integration of understanding.

Merging the two Institutes would also solve what on the surface is an odd but nevertheless important problem. There is way too much separation between the drug abuse and alcohol abuse research communities. They have separate scientific societies that even met for many years in different places but at the same time. True or false, many alcohol researchers believe they should not be applying for grants from NIDA and many drug abuse researchers believe that if they have NIDA grants they cannot get NIAAA grants. This is, of course, silly at best.

What of the arguments that are raised against such a merger? The most common arguments focus on the differences among drugs of abuse. However, as mentioned above, there are as many commonalities as idiosyncrasies, and it is understanding and potentially treating those commonalities that suffer from the separation because the substances and end up being studied way too separately.

A second argument is that the Institutes support different groups of researchers. But that is precisely the problem; there needs to be much more overlap and integration in researchers and research focus.

A third argument reflects concern about potential loss of research funding if the two Institutes were merged. I do believe there would be some savings from administrative economies

[1] Views expressed are those of the author and not necessarily those of the American Association for the Advancement of Science or its members. Affiliation shown for identification purposes only.

of scale, but they would not be as simple as folding one group of administrators into another without taking into account the larger workload or need for extra expertise. There are, after all, specialists in any Institutes; NIDA has cocaine or nicotine experts, so a merged Institute would require an array of experts as well. Moreover, the research budgets should not be reduced since there will be need for more, rather than fewer projects now that work will be done on the commonalities as well as idiosyncratic traits of these substances.

Some individuals have argued that there needs to be a separate alcohol institute since alcohol is a legal substance whereas the substances that NIDA studies are illegal. But NIDA has responsibility for nicotine, which is legal. There also is a related argument that the alcohol beverage industry would oppose a merger because being included with illegal substances would somehow "taint" their products. This does not seem relevant for a public health organization like NIH.

The most coherent question or concern I have heard raised is whether the amount of research devoted to alcohol would, over time, be reduced if that substance became now just one amongst many. The answer is impossible to predict, of course, but the decision to merge should be accompanied by clear instructions to the leadership of the new Institute to guard against such an outcome.

Finally, one could ask whether the current situation is sufficiently "broken" to risk the downsides for the sake of the potential scientific and public health gains that would accompany merger. My response is that acting as if alcohol is somehow unique and that it is not another "drug of abuse" not only delays or diminishes scientific progress but public health progress as well. Every drug has both unique characteristics and traits in common with other abusable substances. It is the commonalities that pose the greatest public health threats and therefore merit much more focused attention.

From:	bk1492@aol.com
To:	SMRB (NIH\OD); AMERICANVOICES@MAIL.HOUSE.GOV; COMMENTS@WHITEHOUSE.GOV; INFO@STARMAGAZINE.COM; TODAY@NBC.COM
Subject:	PUBLIC COMMENT ON FEDERAL REGISTER Fwd: budget should be cut by 50%- fire 50% of high priced bureaucrats who sit at their desks and take surveys with no action ever emanating after this exopesnse
Date:	Friday, February 26, 2010 1:19:22 PM

IT IS TIME SOME RESEARCH IS DOWNGRADED. WHY IS THERE NO PRIORITY LIST THAT THE PUBLIC GETS TO COMMENT ON BECAUSE CERTAINLY THE PUBLIC FEELS THIS AGENCY IS ON THE WRONG FOOT CONSTANTLY.

THERE ARE TOO MANY VACCINES BEING USED WHICH ARE NOT TESTED PROPERLY FOR SAFETY. THEIR ONLY TESTS ARE FROM BIASED PROFITEERS WHO WILL MAKE BIG MONEY FROM THEIR APPROVAL.

AS TO SUBSTANCE USE, TRILLIONS OF DOLLARS HAVE BEEN SPENT ON IT. THAT IS USELESS WITH DRUG FILLED MEXICO SMUGGLING IN TONS AND TONS OF DRUGS TO AMERICA. WE MAY AS WELL DOWNGRADE SPENDING ON THIS.

J. PUBLIC 15 ELM ST FLORHAM PARK NJ07932

Sent: Fri, Feb 26, 2010 7:23 am
Subject: budget should be cut by 50%- fire 50% of high priced bureaucrats who sit at their desks and take surveys with no action ever emanating after this exopesnse

[Federal Register: February 26, 2010 (Volume 75, Number 38)] [Notices]
[Page 8974-8975] From the Federal Register Online via GPO Access
[wais.access.gpo.gov] [DOCID:fr26fe10-79]

DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health 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: March 10, 2010. Time: 8 a.m. to 4:30 p.m. Agenda: Presentation and discussion will include updates from SMRB Working Groups; Deliberating Organization Change and Effectiveness; NIH Intramural Research Program; and Substance Use, Abuse, and Addiction. The Board will also discuss perspectives on organizational change. Time will be allotted on the agenda for public comment. Sign up for public comment will begin at approximately 7 a.m. and will be restricted to one sign in per person. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the contact person address below. [[Page 8975]] Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892. Contact Person: Lyric Jorgenson, PhD, Office

of Science Policy, Office of the Director, National Institutes of Health, Building 1, Room 218, MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, smrb@mail.nih.gov, (301) 496-6837. This meeting is being published less than 15 days prior to the meeting due to scheduling conflicts of the Members. 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 webcast. The draft meeting agenda and other information about the SMRB, including information about access to the webcast, 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 taxis, 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. (Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS) Dated: February 22, 2010. Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy. [FR Doc. 2010-4080 Filed 2-25-10; 8:45 am] BILLING CODE 4140-01-P

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December 17, 2009

Norman Augustine, Chairman
Scientific Management Review Board
c/o Dr. Amy Paterson, Director
Office of Science Policy
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892-0160

Dear Mr. Augustine:

I am writing in my capacity as Chairman of the American Gastroenterological Association (AGA) to express our concerns with the proposal currently being considered by the SMRB to merge NIDA and NIAAA into a single institute. The AGA is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 17,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system. There are several reasons for our concern.

First, we see no scientific benefit that might result from such a merger. AGA members – many of whom are also members of the American Association for the Study of Liver Diseases – conduct important research on the end-organ damage consequences of alcohol. We are very concerned that the opportunity to conduct such research will be lost with a merger.

Secondly, we believe that scientific research will actually suffer. NIAAA is the primary source of funding for extramural liver research on the impact of alcohol. It has funded investigators who have made seminal discoveries in the field. Among them are discoveries that have taught us much about Nonalcoholic Fatty Liver Disease (NAFLD), one of the principal harms found in obesity.

Thirdly, NIAAA is the only institute funding work in the impact of alcohol on patients with hepatitis B and hepatitis C. These two viruses afflict as many as five million Americans (most of whom are undiagnosed). They represent a major public health threat whose risk is exacerbated by alcohol consumption.

Finally, AGA is concerned about the impact of the consideration of this merger on young investigators currently deciding whether or not to enter the field. The level of uncertainty that has been created by this consideration could result in the loss of a substantial amount of intellectual capital from the field of alcohol liver research.

For all these reasons, the AGA respectfully requests that the SMRB bring this issue to a final resolution at the earliest possible date with a recommendation to reject the merger of these two institutes.

Thank you for your consideration of our recommendation.

Sincerely,

Robert S. Sandler, MD, MPH, AGAF
Chairman

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol
Abuse and Alcoholism
5635 Fishers Lane
Bethesda, MD 20892–9304

November 12, 2009

Substance Use, Abuse and Addiction Working Group
Scientific Management Review Board
C/o Office of the Director, National Institutes of Health

Dear Members of the Substance Use, Abuse and Addiction Working Group:

I would like to bring to your attention an individual whose perspective should be heard as part of your deliberations. NIAAA had proposed that Robert Carothers Ph.D., J.D., immediate past president of the University of Rhode Island, be invited to present to the first open meeting of the SUAA working group. Dr. Carothers brings a unique perspective grounded in his decade's long career as a university president.

Unfortunately, Dr. Carothers's schedule precluded him from participating in the September 23rd meeting. At the time, we were assured that he would be given an opportunity to address the working group at a subsequent meeting and therefore did not attempt to fill the vacant slot opposite NIDA's invitee on September 23rd. We then contacted Dr. Carothers who kept October 14th, the date of the next scheduled meeting, open. When NIAAA suggested to the NIH Office of the Director that Dr. Carothers be invited to the October 14th meeting, we were informed that there was not sufficient time available for him to present at that meeting.

Once the agenda for the November 13th meeting of the SMRB was established and we received notice (one week prior to the meeting) that there would be public comment sessions, we contacted Dr. Carothers who offered to attend and address the Board in that format. Given the short notice, he was not able to be present for the full day on Friday, but he generously offered to rearrange his schedule to accommodate travel to Washington D.C. on Thursday evening and participation in the meeting on Friday morning. We broached this with the NIH OD, but were told they could not guarantee that he would be able to present at all during the public comment sessions, let alone ensure that he could have one of the public comment slots in the morning to accommodate his travel. Given the degree of uncertainty, we did not feel it appropriate to encourage him to travel to D.C. for the November 13th meeting.

To reiterate, Dr Carothers has an important perspective that the working group should hear as it moves forward. We therefore hope he would be given the same consideration as previous panelists and be invited to address the board for 10-15 minutes with an opportunity to respond to follow up questions.

Respectfully,

Kenneth Warren, Ph.D
Acting Director and Deputy Director