MUSC
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& BEHAVIORAL SCIENCES

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November 13, 2009

Scientific Management Review Board
National Institute of Health

Dear Board Members,

Thank you for the opportunity to address the Board. My name is Dr. Ray Anton. I am a Distinguished University Professor, Director of the Center for Drug and Alcohol Programs at the Medical University of South Carolina (MUSC), and Scientific Director of a P50 NIAAA-funded Alcohol Research Center. I am a Distinguished Fellow of the American Psychiatric Association, a Fellow in the American College of Neuropsychopharmacology (ACNP), and Vice-Chair of the Board of the ABMRF- The Foundation for Alcohol Research. I am also a recent past President of the Research Society for Alcoholism.

First, I want to thank the members of the Board for their interest and commitment in assisting NIH and all of its grantees, myself included. My association with alcohol could be considered genetic since my grandfather, an Italian immigrant, might have been considered a bootlegger during prohibition. While not an alcohol abuser himself, his attempts to sell liquor cost him his once lucrative canning business. His son, my father, inherited from him a liquor store business where I spent many days of my youth, watching and helping provide alcoholic packaged goods. It struck me then that many people coming to buy beer, wine, and liquor were different—and not in a good way. Therefore, it is somewhat ironic that I found my way to alcohol research, perhaps to undo what my family had unintentionally fostered in so many people. However, this story does point out some important issues.

One issue is that alcohol is a ubiquitous and an ever-present part of our culture with many good, and some not-so-good, aspects. Alcohol use is not going away – we tried that and it failed. Ninety percent of Americans have had exposure to alcohol but 20% of the population consumes 80% of the alcoholic beverages. Therein lies the dilemma – sometimes alcohol does good things, sometimes it does bad things, and many times these are confused and misunderstood. The general population has little appreciation that alcohol works on the brain, never mind that there are exact chemicals and brain areas involved in alcohol dependence. The number one cause of essential hypertension is heavy alcohol consumption, but most primary care doctors are unaware of this and their patients' drinking habits, and therefore, prescribe unnecessary antihypertensives. Alcohol is a leading cause of depression but psychiatrists prescribe unneeded antidepressants. Why? Mostly, because their patients do not tell them about their alcohol use or they do not ask. Reasons behind this are still being detailed but what is clear is that the "stigma" of possibly being labeled an alcoholic plays a large role and weighs on an individual's choice to seek treatment or not. Insurance and employment discrimination continue to be an issue, which we hope the passage of the mental health and substance abuse parity legislation will mitigate. Even if people do seek treatment, medication treatment options are limited and used by only a small portion of the treatment seeking population. The reasons for this are many, but one is that the medications that are available are not universally or powerfully effective. The good news is that ten years ago there were no U.S. pharmaceutical companies interested in developing medications for alcoholism; today there are six to seven large pharmaceutical companies actively engaged in development of medications for alcohol dependence, in large part through NIAAA efforts.

Why am I telling all of this? Well, I am telling all of this to highlight several points that should be considered strongly in contemplating a merger between NIAAA and NIDA. First and foremost in my mind is that alcohol abuse and dependence is just now reaching the early stages of de-stigmatization. We are 15 years behind depression and 20-30 years behind cancer. Second, alcohol permeates all aspects of our health care delivery system. We are just beginning to make inroads into teaching various health care professionals how to screen for, never mind treat, alcohol use disorders. Third, pharmaceutical companies and insurers are just coming around to the idea that preventing and treating alcohol use disorders is a worthwhile and economically sound investment, not to mention being "the right thing to do."

I and many of my colleagues are concerned that public association of alcohol use disorders with other licit and illicit substance abuse will set back the momentum to de-stigmatize and legitimize alcohol prevention (primary and secondary) and treatment. This is an important public health and policy issue which should not be forgotten in the debate regarding a merger of NIAAA and NIDA.

I also want to correct several potential misrepresentations that I saw in the testimony of others as posted on the Board's website. First, it has been stated that most substance abusers are also alcoholics. While this may be true, most alcoholics do not abuse other substances. If one looks at statistics from public clinics, one might come to the first conclusion, but the vast majority of individuals with alcohol use disorders are not in public clinics but are "free-ranging," living and working in our communities. I know this because when we advertise in our local paper or on our local radio for clinical trial subjects, they come out of their "hiding-places" in droves and the vast majority are only addicted to alcohol, not other substances. Second, it has been suggested that all addictions use a common neurochemical and neuroanatomical pathway. While there is some commonality across addictive substances, at this time it would be reductionistic to assume they are "all alike." For instance, we know alcohol is more toxic to neurons than most other abused substances and affects many more neurochemical systems.

Therefore, on both public health and scientific grounds, I think the Board should proceed with great caution and hesitancy to recommend a merger of NIAAA and NIDA. There is likely more to be lost than gained. Complimentary goals and collaborations can be achieved between the Institutes in more constructive and less harmful ways.

Thank you for giving me the time to express my views, and I wish you well in your deliberations.

Sincerely,

Raymond F. Anton, M.D.
Distinguished University Professor
Director of the Center for Drug and Alcohol Programs
Medical University of South Carolina

AMERICAN PSYCHOLOGICAL ASSOCIATION

August 25, 2009

Mr. Norman R. Augustine, Chair
Scientific Management Review Board
Office of the Director
National Institutes of Health

Dear Chairman Augustine,

The Scientific Management Review Board (SMRB) has an extraordinary opportunity to take a fresh look at the organization and allocation of resources at the National Institutes of Health (NIH). We gratefully acknowledge the deliberative approach the SMRB is taking with regard to its charge and we very much appreciate the opportunity to comment on the activities of the SMRB. Although the charters for the SMRB Working Groups have not yet been published, we are writing to the Board to request that the Substance Use, Abuse and Addiction Working Group consider a number of issues that we believe must be addressed in determining whether organizational changes within NIH could further optimize research into substance use, abuse and addiction.

Tobacco

From a scientific perspective, if the rationale to study a proposed merger of NIAAA and NIDA relies on the shared mission and foci of those institutes, then a reasonable extension of that argument is to consider consolidating all research related to tobacco use at NIH. Although NIDA supports the lion's share of that research, NCI funds a substantial tobacco research portfolio too. NCI-funded tobacco research may be weighted toward the medical consequences of tobacco rather than to prevention, etiology of tobacco dependence, or cessation of tobacco use. However, both NIDA and NIAAA have robust programs of research on the medical consequences of drug and alcohol use, respectively, and it would be difficult to argue that the overriding interest in tobacco research at NIH is anything other than its chronic habitual use as a result of nicotine addiction. How would NCI's long-standing tobacco research programs, and those of other Institutes and Centers, be integrated in a proposed reorganization?

Comorbidity

A proposed reorganization must address the high level of comorbidity between substance use and other mental health disorders. As many as 6 in 10 substance users also have at least one co-occurring mental disorder. Research increasingly supports the benefit of studying and treating co-occurring disorders together, with both medication and behavioral therapies. In general, however, the reasons why substance use and other mental disorders coincide so frequently are not fully understood. Epidemiological research suggests that each can contribute to the development of the other. Effective, research-based interventions are being made available for patients with substance use, depression, and certain other co-occurring disorders.

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Steven J. Breckler, Ph.D.
Executive Director for Science

Studies on the root causes of these disorders, common risk factors, and potential interventions will enable us to better serve the large population for whom substance use is only part of the problem. How will the SUAA address a potential merger of NIDA and NIAAA, either structurally or functionally, without also addressing comorbidity and the relationship between the NIDA/NIAAA portfolios and that of NIMH? How would NIMH's programmatic long-standing interests in comorbidity and those of other Institutes and Centers, be integrated in a proposed reorganization?

Other compulsive/habitual behaviors

Recent studies illustrate the similarity of addiction to some disorders that are not associated with pharmacologic substances. For example, compulsive behavior and poor choices are hallmarks of obsessive-compulsive disorder and pathological gambling. These disorders, too, are characterized by disruption of the frontal lobe's capacity for reason and control. The emerging picture of addiction as a disease of compulsion and disrupted control and not merely pursuit of pleasure suggests new possibilities for treatment and may suggest targets for pharmacological or behavioral therapies to modulate signaling that results in compulsive behavior or destructive choice. Where are the lines drawn between substance use, abuse and addiction and other compulsive/habitual behaviors (e.g., gambling, sex, eating, gaming, social networking)? Where does that portfolio reside now? Would a reorganization embrace all research related to compulsive/habitual behavior? If not, what is the scientific rationale for excluding that research from a proposed reorganization of substance use, abuse and addiction research?

In closing, optimizing the organization and management of substance use, abuse and addiction research at the NIH is a goal that the APA wholeheartedly supports on behalf of psychologists who conduct the science as well as those who will ultimately use the science to improve the health of their patients. We commend the Board for its willingness to assume the challenging task ahead and appreciate its consideration of the complex inter-relationships a thorough review of that research portfolio will reveal. Please feel free to contact me or Dr. Geoff Mumford (gmumford@apa.org), Associate Executive Director for Government Relations, if we can be of further assistance as you continue your deliberations.

Sincerely,

Steven J. Breckler, Ph.D.
Executive Director for Science

The National Center on
Addiction and Substance Abuse
at Columbia University

(1)

October 28, 2009

Norman Augustine, MS
Chair
Scientific Management Review Board, OD, NIH
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dear Mr. Augustine:

I am writing to you and the Scientific Management Review Board to provide my strong support for merging the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism. Merging and integrating these two organizations will help the National Institutes of Health better focus on all addictive substances including alcohol, tobacco, controlled prescription drugs, illicit drugs and other drugs of abuse.

I have been a strong proponent of a combined institute for many years. In my 1986 book, *America's Health Care Revolution*, I argued that creating one institute for all addictions would "help generate a steady stream of money for research, make clear our national commitment, and attract more of our best minds to the effort." Since then, I have called repeatedly for the creation of such an institute through newspaper opinion pieces and in my book *Radical Surgery* in 1994, arguing further that a combined institute would eliminate many of the bureaucratic bouts over turf that slow and sometimes kill valuable research projects.

Merging the institutes is an idea long overdue and one that only has been bolstered by the growth of scientific knowledge. Science clearly demonstrates that the disease to be addressed is addiction--that alcoholism or dependence on tobacco, cocaine or other drugs are all manifestations of that condition. In the real world, few people use only one substance. The pathways to addiction frequently involve multiple substances and, among dependent users, there is significant substitution of drugs of abuse.

CASA's 17 years of research on substance abuse and addiction has found that examining only one substance or class of drugs can have a blinding effect. For example, while America was congratulating itself on reductions in marijuana and other illicit drug use, abuse of controlled prescription drugs skyrocketed, catching policy makers, prevention services providers and the treatment community off guard. Creating one national institute focusing on all substances of abuse will free researchers to examine the pathways to addiction, prevention strategies, pharmacological and behavioral treatment

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and their efficacy, and appropriate policy responses across drugs of abuse. A broader research focus on substance abuse and addiction instead of on specific substances of abuse might also prove to be a more cost-effective way to understand the disease. Above all, the National Institutes of Health should be driven by the science and most effective ways to serve our nation and all its citizens.

Sincerely,

Joseph A. Califano, Jr.

Cc: Nora D. Volkow, MD

Kenneth R. Warren, PhD

Ian M. Colrain Ph.D.
Associate Director,
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4/17/2009

Raynard S. Kington M.D.
Acting Director, National Institutes of Health.

RE: NIH Scientific Management Review Board meeting.

Dear Dr. Kington,

I am writing in regard to the proposed merger of NIAAA and NIDA, and hope that the board would consider the following, when making its recommendation. In the sprit of full disclosure, I am the PI on two grants from NIAAA (AA17320 and AA14211) and co PI on a grant from NIDA (DA16427).

Alcohol has been a part of the social, political and economic fabric of America since colonial days, and Americans have a nuanced, if not ambivalent, relationship to alcohol. From the Whiskey Rebellion of 1794, to nineteenth century temperance movement, to the 18th and 21st amendments to the constitution, to the California wine industry, alcohol use and abuse are embedded in the culture.

Alcohol is imbued with positive attributes in religious ceremonies, social gatherings and even political events with toasts to foreign dignitaries. Conversely, its excessive use is eschewed with contempt for public drunkenness. Alcohol use in moderation has health benefits and use in excess can be ultimately lethal, and alcohol abuse (without necessary dependence) is a contributing factor to many diseases including hypertension, stroke, cancer and heart disease. In addition to the personal deleterious health effects of alcohol abuse, too often we read of, or are directly effected by, the tragic death of the innocent by-stander who was not drinking but was killed by an intoxicated driver. Much of the public health concern about alcohol abuse does not involve addiction, but rather the untoward and often tragic consequences of its acute misuse with automobile accidents, boating accidents, drowning and acute alcohol poisoning.

The very existence of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) recognizes the prominent and special, social and cultural role of alcohol in America. The merging of NIAAA with another institute could send a message to the public that concerns about the problems of alcohol abuse are of lesser importance, and it runs the risk of diminishing the amount of research dedicated to understanding both the beneficial and the

deleterious effects of alcohol and diluting the public health mission of alcohol abuse detection, prevention and treatment.

I would respectfully suggest, that maintaining NIAAA as a separate institute is in the best interests of the NIH and the public health of the United States.

Yours sincerely,

Ian M. Colrain Ph.D.

UNC
SCHOOL OF MEDICINE
BOWLES CENTER FOR
ALCOHOL STUDIES

Dear SMRB,

I have been asked by the Research Society on Alcoholism to comment on how a merger of NIAAA to NIDA would impact the research of the Bowles Center for Alcohol Studies at the University of North Carolina School of Medicine. I am Director of the Bowles Center and the John Andrews Distinguished Professor and a Professor of Pharmacology and Psychiatry. I am also Principle investigator of an NIAAA P60 Alcohol Research Center in its 12th year of funding and an Alcohol Research training grant in its 11th year of funding. Our Center is focused on alcohol related pathologies. My faculty believe that a merger of NIAAA and NIDA will decrease alcohol research on health and have a negative impact on alcohol research.

Our alcohol research center has always included components working on fetal, liver, and brain pathology. Cellular and molecular mechanisms of alcohol pathology involve oxidative stress mechanisms and immune gene expression that contribute to various pathologies. My faculty have been funded by NIDDK, childhood disorders, NIMH, NIA, NIEHS and other institutes, but to my knowledge no faculty member in our Center has ever been funded by NIDA. A merger would reduce research on alcohol and health.

If institutes are merged research on alcohol induced liver disease will stop. Liver pathology researchers have already begun to shift their efforts to NASH, non-alcoholic steatohepatitis, funded by NIDDK. A merger will largely end fetal alcohol research, a major part of the NIAAA portfolio. FAS scientists will shift to other teratogens funded by NIEHS or childhood disorders or to nutritional deficiency teratogenic disorders. Alcohol brain pathology scientists at our center focus on anxiety, depression and alcohol induced neurodegeneration. Our focus is not on dependence, but more on mental psychopathology induced by alcohol. Some would write NIDA grants, however, most would continue to the focus on pathology and stop studying alcohol. Neurodegeneration and/or psychopathology are funded through NIMH, NIA and NINDS. Alcohol brain pathology research will suffer in a merger.

Most Americans drink alcohol. Alcohol is unique in being both a drug and a food. Understanding the health impact of alcohol is important to guide public policy to improve the health of Americans. A merger of NIAAA and NIDA will reduce research on alcohol and health.

Our faculty in Family Medicine are working on screening and brief intervention and treatment for heavy drinking as a risk for health. The effort is similar to measuring blood pressure for risk of CV disease and weight for risk of diabetes. Heavy drinking has health risks for oral cancers, liver disease, mental disorders, and likely many other unknown negative health risks. Efforts for primary care physicians directed at alcohol related risk of disease will be lost in drug addiction criminal justice issues.

Our clinical trials on medications to reduce drinking recruit heavy drinkers, often not seeking treatment, through the newspapers. Most are employed and do not use drugs of abuse. The goal to reduce heavy drinking, relapse to heavy drinking and total numbers of drinks per week are markedly different from stimulant abstinence or opiate substitution therapy. Alcoholics Anonymous and Narcotics Anonymous are separate volunteer support groups that highlight the

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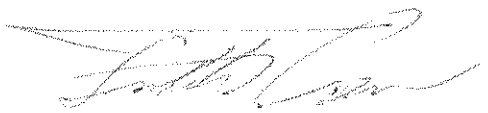
differences between alcohol and stimulant-opiates. Thus, clinical prevention and therapeutic efforts on healthy levels of alcohol drinking will suffer from a merger of NIAAA to NIDA.

Finally, a merger will reduce alcohol research training. The food component of alcohol, e.g. calories, the volume of alcohol consumed and animal aversion to alcohol make research on alcohol particularly unique and complicated. These complexities and others make it very difficult for people not trained in alcohol research to do alcohol research. A merger will shift the emphasis to drug abuse and training in alcohol research will suffer leading to a loss of alcohol research expertise.

In summary, a merger will negatively impact alcohol research on health. Alcohol is consumed by most Americans. It is important to know the impact of alcohol on health to guide public policy to improve the health of Americans.

Thank you for the opportunity to express these thoughts.

Sincerely,



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October 12, 2009

Dr. William Roper
Chairman
Substance Use, Abuse, and Addiction Workgroup
Scientific Management Review Board, OD, NIH
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Roper:

The National Organization on Fetal Alcohol Syndrome (NOFAS) is troubled by the growing reports that representatives of NIDA have publicly portrayed the possible merger of NIAAA and NIDA as a "done deal" that enjoys the avid support of NIH leadership. I understand, for example, that NIDA officials have been commenting over the past year at symposia and professional association meetings that the merger is inevitable and that such comments may have played a role in shaping organizational positions on the merger.

Indeed, Dr. Darrell Regier, Executive Director of the American Psychiatric Institute for Research and Education, and Director, Division of Research, American Psychiatric Association (APA), stated the following in a note to members who dissented strongly with the APA endorsement, *"with regard to the proposed merger, the Council's carefully considered the fact that both the IOM and the NIH leadership have strongly supported this merger with the likelihood being high that it will be approved"*. Similarly, I note that Dr. Alan Leshner, who had only recently stepped down as director of NIDA, was a key participant in the development of the IOM recommendation.

These reports are troublesome on several levels. First, they undermine the integrity of the comprehensive process which the Scientific Management Review Board (SMRB) has put in place to methodically assess the need for and merits of a possible merger of the institutes. If the results of the process are pre-ordained, the substantial time and resources dedicated to this effort by SMRB, the Substance Use, Abuse and Addiction Workgroup (SUAA) and, of course, the numerous stakeholders, are wasted.

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Second, such comments chill open and objective debate about the issue. If interested parties are led to believe that the merger is a fait acompli, they may color their commentary so as not to offend NIH leadership or the leaders of the surviving institute. Worse yet, such comments may dissuade stakeholders from participating in the discourse at all. Finally, such remarks subvert Congressional intent, as expressed in the NIH Reform Act of 2006, that the SMRB rigorously review and objectively assess the extent to which NIH should exercise its organizational authorities. If the merger is inevitable, the SMRB efforts are superfluous.

NOFAS urges you in the strongest possible terms to take steps to ensure that the air of inevitability which some suggest has settled over these deliberations is quickly dispelled.

NOFAS appreciates SUAA's exhaustive work on this critical issue and looks forward to continued active participation in the process.

Sincerely,

Tom Donaldson
President

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November 10, 2009

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

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

Dear Review Board Chair and Members of the Subcommittee:

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

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

A national program supported by The Robert Wood Johnson Foundation® with direction and technical assistance provided by the Department of Psychiatry and Behavioral Sciences at The Johns Hopkins University School of Medicine

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Jack E. Henningfield

Jack E. Henningfield, Ph.D.
Director and Professor, Adjunct
Innovators Combating Substance Abuse Awards Program
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and
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Jefferson University Physicians

November 13, 2009

Scientific Management Review Board
National Institute of Health

Dear Board Members,

Thank you for the opportunity to present my views on the issue of a merger between NIAAA and NIDA. My name is Jan Hoek. I am a Professor of Pathology, Anatomy and Cell Biology at Thomas Jefferson University in Philadelphia. I am a cell biologist with an interest in cellular metabolism, cell signaling, cellular stress response and cellular systems biology, so very much on the basic science end of the spectrum of people who are addressing you here today. I have been active in alcohol research for over 25 years and received continuous grant support from NIAAA through all those years. I have been a member of the NIAAA National Advisory Council and have been active in various other national organizations that stimulate alcohol research. However, I also receive funding from other NIH institutes, including NIGMS, I have been a member of the NIH Fatty Liver Disease working group and I am on the boards of a number of international Systems Biology research initiatives that are active in hepatology and cancer research.

From a health perspective, alcohol is truly remarkable and different from any other drug. Even with moderate drinking that is tolerated readily, our bodies accumulate alcohol in concentrations higher than almost any other compound (except for water). It is the chronic exposure to high concentrations of alcohol that is responsible for a lot of the organ pathology that is a predominant contributor to the disease burden of alcohol. This pathology is evident in liver, heart, skeletal muscle, pancreas, lung, the immune system, the gut, and even in the brain. None of these organs operates in isolation and the actions of alcohol on liver metabolism directly impact on its effects on the brain, the gut, the immune system and so on. Moreover alcohol affects the susceptibility to a variety of other severe diseases conditions. Very well known is, of course, the impact of chronic alcohol use on the disease progression with hepatitis B and hepatitis C infections. Alcohol is a risk factor for a variety of cancers, including breast cancer. We don't really understand the mechanisms underlying these actions of alcohol, but it is apparent that the public health burden of alcohol abuse is much broader than can be captured under its addictive effects. These systemic alcohol effects can only be understood with a broad based research approach. NIAAA has been a critical player in supporting research that has enabled us to appreciate the systemic nature of alcohol effects.

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At Thomas Jefferson University and more broadly in the Delaware Valley region, we have been able to recruit, over the past 25 years, a very interactive group of basic researchers in cell biology, hepatology, biophysics and computational systems biology who have an active interest in studying the impact of alcohol on cell and tissue function. Similar groups exist around the country that have been able to come together almost entirely thanks to the tremendous support that NIAAA has given for the study of basic research into the health effects of alcohol. The goal of all these research efforts is to understand the causes of the functional disruptions, from the molecular and cellular level to the tissue and organism level, that can contribute to this multi-organ alcohol-related pathology. None of these studies could even remotely be captured under the heading of addiction research. If the NIAAA were to be merged with NIDA to form a new institute with a focus on addiction, research support for these critical health effects of alcohol would dwindle. Without grant support for alcohol research the number of researchers who can be recruited to study the cellular and molecular basis of this important health problem will dwindle. This will be a tremendous loss to our nation. For these reasons, I urge you not to support the merger of NIDA and NIAAA.

Thank you.

Jan B. Hoek, Ph.D.

May 27, 2009

Dear Chairman Augustine and members of the SMRB –

My name is Jennifer Monti and I am a fourth year medical student at the Cleveland Clinic Lerner College of Medicine, Case Western Reserve University. This program is a unique 5-year MD program that emphasizes research training. I am also obtaining an MPH during the course of my training. My education is funded through an NIH Physician-Investigator Training Grant to the Cleveland Clinic. I am the, young potential PI that the SMRB discussed at its April meeting. I write to offer three comments and two specific recommendations on actions the SMRB can take to gather data to guide its recommendations on how to successfully attract and retain young clinical investigators.

31 colleagues and I entered our medical school training with a specific interest in research training. My enthusiasm for such a career has waned, rather than increased, throughout the course of training. The key obstacle to my interest in pursuing an academic research career is a *clear lack of leadership opportunities* within academic medicine for young leaders. The central message of medical training is to wait.

It is difficult to see a path towards leadership in a bureaucratic system that generally requires a young investigator to ride someone else's coattails into the safe harbor of tenure or to hopes of a self-sustaining grant. There seems to be no place for young participation in leadership groups. I may have been the only person in the room at the SMRB meeting who was under 30 years old. Yet, the lack of young investigators is precisely a key problem underlying the clinical research enterprise. Would the SMRB have dismissed out of hand the comments of a young scientist who was invited to sit at the table? Or is that perspective welcome? Or does the SMRB think it knows enough of what needs to be done to retain people like me? Is there no place for young people to weigh in on the organizational structure of NIH and its relationship to future research success? I would opine that a younger generation's input is crucial to questions #1 ('what would the NIH look like de novo) and #3 (Intramural Center and Clinical Center) that the SMRB agreed to take up in its work.

It may be possible to re-engage young physician investigators by inviting them to participate in discussions on the future of NIH organizations to optimize research processes. I ask the SMRB to consider the benefit versus the burden of seating a young trainee at the table with older voices. In the best case, the younger voices will add unique perspective that may prevent NIH from creating obstacles rather than opportunities. In the worst case, the opinions of the younger voices are shouted down and saved for a later date.

Second, there is concern among young scientists that it is more important to work with someone who has an important name than someone who has good ideas. Several classmates of mine have had to battle with program administrators to work in research environments with scientists who do not have years of experience. This simply reinforces the idea that the best way to get along is to go along, and those who have been around the

longest must have the best ideas. The SMRB must examine the willingness of NIH to grant autonomy to researchers at a younger age and invest in a mentorship model for younger investigators rather than a single PI-subordinate model. I would propose the development of an innovator grant titled, '30 under 30', or something equally catchy to empower young investigators to pursue their own ideas. 30 researchers, 300,000 apiece, for 3 years, to make their own decisions in collaboration with a more senior PI who advises but does not make final decisions. NIH would essentially be funding 30 start-up organizations. What is the benefit versus the burden of a such an approach?

Third, peer review is intended to be a democratic process, and it ought to remain the backbone of grant making in the NIH community. However, I was struck by the comments that study sections fund the most predictable science. Why should we expect people who have been successful with one model to suddenly decide to fund something that is in a radically different vein? This reminds me of the classic problem of innovation in industries – perhaps Mr. Augustine will appreciate the analogy? The large steel mills missed the boat on flexible, more innovative ways to make steel. They saw the smaller technologies as peripheral to their core business, so they let those segments of the market go. In time, there was no comparative advantage for the large steel companies. Blockbuster missed Netflix, Kentucky Fried Chicken missed the grilled chicken sandwich, and Microsoft underestimated the Internet. Why should we expect the large NIH, the same faces of study sections, even senior faces, to be comfortable with something that looks different and has not been successful before? Why change what is, from the perspective of the owners, a good system that has reaped modest, predictable rewards for those in power?

I propose an experiment on peer review. Thousands of grants have recently come in through the Challenge Grants program. NIH will review the proposals through traditional channels. I propose to form a small group of physicians and scientists in training to evaluate the same stack of grants and make recommendations and scores on the grants. What if the two groups of reviewers come up with very similar rankings? What does that say about the need for highly seasoned reviewers? Could the data spur the inclusion of younger scientists in leadership positions to make them more invested in research process and outcomes? Perhaps the grants would be ranked in a radically different order by the traditional and younger groups; this data would offer an innovative perspective on what each group valued in the ranking processes.

SMRB is charged with evaluating how the structures of the NIH can be optimized to further the research prowess of the organization. Autonomy and inclusion of young researchers is crucial to their investment in the processes and outcomes of research. Inclusion of young people in decision making bodies, unique funding channels, and peer review processes would begin to signal that the NIH culture is transforming from a stodgy, bureaucratic, clubby vehicle to an institution that seizes new ideas, leaves rank at the door, and welcomes new voices.

If young people are not invested, no changes in organizational structure can will us to engage. We will not come just because it is built properly. We will only come if we helped build it.

Thank you for your work and the opportunity to comment.

Best regards,

Jennifer Monti
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INTERNATIONAL CERTIFICATION &
IC&RC
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Dear Dr. Augustine: November 6, 2009

As you deliberate on the subject of the potential merger between the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA), we are pleased to offer our opinion on the subject. The International Certification and Reciprocity Consortium (IC&RC) gives its full support to this potential merger.

IC&RC is a consortium of over 70 certification boards that in turn certify close to 40,000 substance abuse counselors. Our boards are present in 44 states, 4 branches of the armed forces, 3 tribal nations, and 13 foreign countries. In addition to certifying professionals in substance abuse treatment, we also offer credentials in prevention, as well as criminal justice, and clinical supervision. Our mission to establish and advance public protection through standards for the credentialing of professionals engaged in the prevention and treatment of substance use disorders and related problems can only be furthered by such a merger.

As representatives of the addiction treatment community, we have a great stake in the future of research. The quick, efficient dissemination of research to practice is of critical importance to our members and the populations they serve. The research of addiction, to any substance, is a critical piece of the puzzle that is our nation's collective health. A merger of these institutes will only increase the profile of the disease of addiction. Even today, after all of our advances and all of the stigma we have fought, our field continues to struggle for recognition as a deadly disease. By merging the NIAAA and the NIDA, we will have one institute dedicated to one disease, just as other diseases, such as cancer and diabetes, have theirs.

We support this potential merger with the full expectation that funding for addiction research will not suffer as a result, and nor will the integrity of the research. We hope that a merger will make this research more efficient, especially in the arena of dissemination and translation into practice. We also hope it will increase the portfolio of co-morbidity research and treatment, which remains a key cog in the treatment machine.

Our confidence is high that you and the SMRB will in the end do what you believe is best for the future of science and research. Whatever the result, we respect your endeavor and again thank you for the opportunity to comment.

Sincerely,

Rhonda Messamore, President
International Certification and Reciprocity Consortium

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RSA PRESIDENT:
Sara Jo Nixon, Ph.D.
Professor and Chief, Division of Addiction Research
Department of Psychiatry, University of Florida
352-392-3681 sjnixon@ufl.edu

July 29, 2009

Mr. Norman R. Augustine
Chairman
Scientific Management Review Board
Office of the Director
National Institutes of Health
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dr. William R. Brody
Chairman
Deliberating Organizational Change Workgroup
Scientific Management Review Board
Office of the Director
National Institutes of Health
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dr. William D. Roper
Chairman
Substance Use, Abuse, and Addiction Workgroup
Scientific Management Review Board
Office of the Director
National Institutes of Health
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dear Chairmen Augustine, Roper, and Brody:

I am writing on behalf of the Research Society on Alcoholism ("RSA") to recommend several individuals who are qualified to serve as expert advisors to the Substance Use, Abuse, and Addiction Workgroup ("SUAA") and the Deliberating Organizational Change Workgroup ("DOC) as they address the critical issues with which they have been charged by the NIH Scientific Management Review Board ("SMRB").

RSA was established in 1976 to serve as a meeting ground for scientists working in all fields of alcoholism and alcohol effects. The Society represents over 1700 scientists, physicians, academics,

and other experts who are committed to understanding and intervening in the consequences of alcohol through basic research, clinical protocols, and epidemiological studies. For many years, RSA has worked closely with the National Institutes of Health, the National Institute on Alcohol Abuse and Alcoholism ("NIAAA"), the Department of Veterans Affairs, and the Department of Defense to stimulate and pursue research initiatives concerning alcoholism and the effects of alcohol.

RSA has drawn on its considerable expertise with alcohol-related matters as well as its extensive experience with hundreds of physicians, scientists, and leaders in the field to prepare the list of potential experts proffered below. RSA unqualifiedly recommends each of these individuals to SMRB and the SUAA and DOC Workgroups. Please note that RSA has limited its candidates to only senior experts who are well-qualified to present substance use research in the long-term and have demonstrated expertise in organizational growth and structure. Each of these individuals is well-able to participate in a meaningful way in discussions concerning the process of structural change, the development of meaningful objective criteria for assessing restructuring proposals, and the potential impact of changes at all levels of NIH responsibility.

Recommended Experts for SUAA Workgroup

Raul Caetano, M.D., Ph.D.

Dr. Caetano is Professor of Health Care Sciences and Dean of the Southwestern School of Health Professions, University of Texas Southwestern Medical Center, and Professor of Epidemiology and Regional Dean of the Dallas Regional Campus, University of Texas School of Public Health. His is an alcohol epidemiologist with a special interest in drinking and alcohol-related problems among ethnic minorities.

Michael Charness, M.D.

Dr. Charness earned his B.Sc. in Psychology from McGill University (1972) and his M.D. from the Johns Hopkins University School of Medicine (1976). Following a residency in Internal Medicine at the Johns Hopkins Hospital (1976-78), he served as resident and Chief Resident in Neurology (1978-81) and postdoctoral fellow in Neuroscience (1981-83) at the University of California, San Francisco. He is board certified in Internal Medicine and Neurology. Dr. Charness was Assistant Professor of Neurology at UCSF before moving to the Brockton/West Roxbury VA in 1989. He was appointed Chief of Neurology at the Brockton-West-Roxbury VA (1996-1999) and subsequently at the VA Boston Healthcare System (1999-2003), which was formed through the merger of the Boston VA and the Brockton/West Roxbury VA medical centers. In 2003 he was appointed Chief of Staff at the VA Boston Healthcare System, where he is responsible for all clinical, education, and research programs. Dr. Charness is Professor of Neurology and Faculty Associate Dean at Harvard Medical School and Assistant Dean at Boston University School of Medicine.

Dr. Charness's laboratory has enjoyed continuous support from NIH and the VA to study the molecular and cellular mechanisms of alcohol toxicity in the nervous system and the development of drugs that block alcohol neurotoxicity. His research has focused on the interactions of ethanol with the L1 neural cell adhesion molecule, a molecule that is critical for development of the nervous system. After noting similarities in the neuropathology of children with L1 gene mutations and fetal alcohol

syndrome, his lab demonstrated that ethanol inhibits L1 adhesion at concentrations attained after ingesting one or two alcoholic beverages. Drugs and peptides that antagonize ethanol inhibition of L1 adhesion also prevent ethanol-induced teratogenesis in mouse embryos. In recent work, Dr. Charness and colleagues have characterized an alcohol binding pocket within the extracellular domain of L1, a short distance from disease-causing loci.

Dr. Charness is the scientific director of the NIAAA Consortium Initiative on Fetal Alcohol Spectrum Disorders, an international effort to improve the diagnosis, prevention, and treatment of this condition. He was President of the Research Society on Alcoholism (2005-2006) and serves on the Board of Directors of the International Society for Biomedical Research on Alcoholism (2002-2010). He was awarded the Frank Seixas Award of RSA (1999) and a MERIT Award from NIAAA, NIH (2002). He was a member and Chair of the Alcohol-Toxicology 3 Study Section, NIH (1997-2000) and Chair of the Medical Advisory Council, Alcoholic Beverage Medical Research Foundation. He served on the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effects (2000-2003) and is a member of the National Advisory Council for NIAAA (2005-2009).

Mark S. Goldman, PhD

Mark S. Goldman is Distinguished Research Professor and Director of the Alcohol and Substance Use Research Institute at University of South Florida (USF). He also served as Associate Director of the National Institute on Alcohol Abuse and Alcoholism from June, 2003, until May, 2006, and as Director of Clinical Psychology Training at USF from 1985 - 1995. He received his Ph.D. in January, 1972, from Rutgers University and has been on the faculty at Wayne State University (1973-1985) and USF (since 1985). He is a fellow of Divisions 3, 6, 12, 28, and 50, a member of 40 of the American Psychological Association (APA), and is board certified (ABPP) in clinical psychology.

In addition to research and clinical work in the addictions field since 1969, Dr. Goldman has served as Psychology Field Editor for the *Journal of Studies on Alcohol*, consulting editor (masthead) of a number of APA journals, member and then chair of the Psychosocial Research Review Committee of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), member of NIAAA's National Advisory Council on Alcohol Abuse and Alcoholism, chair or member of a number of NIAAA portfolio review committees, member of the NIAAA research priority committee, co-chair (with Father Edward A. Malloy, president of the University of Notre Dame) of the NIAAA subcommittee on College Drinking, member of the Board of Professional Affairs of the APA, member of the Task Force on Psychological Intervention Guidelines (APA), President of the Division on Addictions for APA, and member and then chair of the psychosocial advisory review group for the Alcoholic Beverage Medical Research Foundation. In 1992, Dr. Goldman received a MERIT Award from the NIAAA. Dr. Goldman's major research interest is in alcohol expectancies and cognitive mediators of alcoholism risk, and the development of drinking and risk for drinking in children, adolescents, and young adults (over 300 articles and presentations)

Edward P. Riley, PhD

Edward P. Riley (Ph.D., 1974, Tulane University) is currently a Distinguished Professor in the Department of Psychology and the Director of the Center for Behavioral Teratology at San Diego State University. He has authored over 225 scientific papers and reviews, primarily on Fetal Alcohol

Spectrum Disorders. He was the Chair of the U.S. National Task Force on FAS/FAE from 2000-2004 and currently serves on the Expert Panel for the SAMHSA FASD Center for Excellence. He has served as President of the Research Society on Alcoholism, the Fetal Alcohol Study Group, and the Behavioral Teratology Society. He is currently a Reviewing Editor and on the Editorial Board of *Alcoholism: Clinical and Experimental Research*. He has received numerous awards for his scholarship and service including the Research Society on Alcoholism Distinguished Researcher Award and the National Organization on Fetal Alcohol Syndrome Research Recognition Award. His work on FASD has been continually funded by the National Institute on Alcohol Abuse and Alcoholism since 1978.

Marc A. Schuckit, M.D.

Dr. Schuckit is the Distinguished Professor of Psychiatry at the University of California, San Diego School of Medicine as well as the Associate Director of the Alcohol and Drug Treatment Program at the San Diego Veterans Affairs Medical Center. His major area of work includes genetic and environmental contributors toward alcoholism, comorbidity between alcohol/drug and psychiatric conditions, and diagnostic issues in the substance use disorders. He has served as the chairperson of the DSM-IV Substance Use Disorders Workgroup, and is a member of the DSM-V Substance Use Disorders Workgroup. On a national and international level, Dr. Schuckit serves as the Editor of the *Journal of Studies on Alcohol and Drugs*, has twice been a member of the Advisory Council for NIAAA, and has served as a member of NIH grant application review committees.

Gyongyi Szabo, MD, PhD

Dr. Szabo, is Professor of Medicine and Associate Dean for Clinical and Translational Research at the University of Massachusetts Medical School where she also serves as Director of the MD/PhD program and Director of Hepatology and Liver Center. Dr. Szabo is an expert on the health and end-organ effects of alcohol use. She studies the effects of acute and chronic alcohol use on regulation of immunity and inflammation and the relationship between alcohol use and other liver diseases including non-alcoholic fatty liver disease and viral hepatitis infection. She studies the molecular and cellular mechanisms of alcohol- and hepatitis C- induced modulation of inflammation and the role of Toll-like receptor signaling pathways in alcoholic liver disease and in alcohol-induced acceleration of hepatitis C virus infection. Her studies on alcohol-induced modulation of inflammation have wide implications to the end-organ effects of alcohol use as related to the brain, lung, hart, pancreas, adipose and liver. She is an internationally recognized leader in the field of liver immunology and has been organizer and invited speaker at numerous international and national conferences, published papers in the highest ranking journals in the field liver research.

Dr. Szabo is a leader in alcohol research, she has been the organizer of the satellite meetings of the Research Society on Alcoholism (RSA) in the last 6 years and she is also Associate Editor of the journal of the RSA, *Alcoholism, Clinical and Experimental Research*. She has served on the External Advisory Board of the NIAAA. Dr. Szabo has leadership roles in the American Association for Liver Diseases (AASLD) as previous Chair of the Basic Research Committee and currently as Chair of the NIH Liaison Committee. Dr. Szabo is Associate Editor of *Hepatology* and she has served as member of Liver Action Plan and the National Commission for Digestive Diseases for the NIDDK.

Recommended Experts for DOC Workgroup

Kathleen Grant, Ph.D.

Dr. Kathleen Grant is Professor of Behavioral Neuroscience and Senior Scientist at the Oregon National Primate Research Center and the Oregon Health & Sciences University in Portland Oregon. Although she has been consistently supported by the NIAAA since a graduate student, both as an Intramural Staff Scientist and as an Extramural grantee, Dr. Grant also received training in behavioral pharmacology under the past NIDA Director, Dr. Charles R. Schuster, and is well versed in the behavioral pharmacology of all drugs of abuse. Dr. Grant has been the director of programmatic funding from NIAAA including training grants, a Center grant and currently a Consortia grant addressing the neural basis of stress and excessive alcohol consumption. Dr. Grant has received numerous awards and honors including the Keller and Bolles lectureships, the President of the Research Society on Alcoholism, and the Chair of the Board of Scientific Counsel for NIAAA. Dr. Grant has expertise in developing and applying animal models of alcoholism to advance our understanding of the risk for and consequences of excessive drinking. Her research highlights the unique effects of alcohol, unlike any other drug of abuse, on the entire of physiology of the organism, including the effects on nervous, reproductive, cardiovascular and digestive systems in understanding the diseased states propagated by the abuse of alcohol. Her research on endogenous steroids that mediate the subjective state of intoxication is a key finding in the understanding the insidious nature of alcohol in vulnerable individuals that propagates the abnormal drinking associated with alcoholism.

R. Adron Harris, Ph.D.

Adron Harris is the M. June and J. Virgil Waggoner Professor of Neurobiology and Cell and Molecular Biology as well as the Director of the Waggoner Center for Alcohol and Addiction Research at the University of Texas in Austin, Texas. His research areas include the neuropharmacology of alcohol, genetics of alcohol action, and brain mechanisms of alcohol dependence. He is very active in relevant national and international organizations--he is the Immediate Past President of the International Society on Biomedical Research on Alcoholism (ISBRA), a Past President of RSA, and a current member of the NIH/NIAAA National Advisory Council

Victor Hesselbrock, PhD

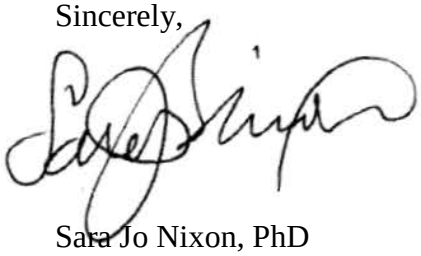
Victor Hesselbrock, PhD (PhD, 1977, Washington University (St Louis)) is currently Professor and Vice Chairman, Department of Psychiatry, University of Connecticut School of Medicine. He also holds the Physicians Health Services endowed chair in Addiction Studies. Dr. Hesselbrock is the Principal Investigator and Scientific Director of the University of Connecticut's NIAAA funded Alcohol Research Center and is co-Principal Investigator of the national Collaborative Study on the Genetics of Alcoholism (COGA). He is a past President of the Research Society on Alcoholism, and served on the National Advisory Council for the National Institute of Alcohol Abuse and Alcoholism (NIAAA) and the NIH Council of Councils. Dr. Hesselbrock is Associate Editor of *Alcoholism: Clinical and Experimental Research*, a Review Editor for *Addiction*, and a member of the editorial board of the *Journal of Studies on Alcohol and Drugs*. He has published more than 275 peer-reviewed articles. His research interests include: the genetic epidemiology of alcoholism; co-morbid psychiatric

conditions and substance dependence; and psychosocial, cognitive, and genetic risk factors for developing alcohol dependence and alcohol-related problems. His work on alcohol and substance abuse has been continually funded by the National Institutes of Health (including NIAAA and NIDA) since 1978.

RSA appreciates the opportunity to recommend experts who can assist SMRB and the SUAA and DOC Workgroups in their important missions. We would be pleased to provide any additional information concerning these candidates.

RSA welcomes the chance to work closely with each of you in the coming months.

Sincerely,



Sara Jo Nixon, PhD
President
Research Society on Alcoholism

From: Charles O'Brien [mailto:obrien@mail.trc.upenn.edu]
Sent: Monday, May 04, 2009 2:57 PM
To: Tabak, Lawrence (NIH/OD)
Subject: Review board meetings for consideration of NIAAA-NIDA merger

Dear Dr. Tabak,
It has come to my attention that your committee is interested in obtaining opinions on the advisability of the merger of the two institutes involved in research on substance use disorders. I am writing to offer my services if you would like to hear from someone who has been doing research on all forms of drug abuse including ethanol for the past 40 years and has served as an adviser many times to both institutes.
I was a member of the committee in the 1980s that formed the modern definition of alcohol dependence and am currently the chair of the APA committee that is revising the definition for a new edition to come out in 2012.

In brief, I have been an active alcohol researcher since 1971, but I have never limited my research to the single drug, ethyl alcohol. In the past decade and a half it has been difficult to find pure alcoholics to study. Most patients are dependent on alcohol plus other drugs. For political reasons, we can't usually mention this in alcohol applications, but we have always been permitted to study alcohol along with other drugs on NIDA grants. This is how we discovered that naltrexone is effective in alcoholism. It might never have been discovered otherwise because naltrexone was known at that time as a "heroin drug." It is now used all over the world to treat alcoholism.

It is a complete waste of taxpayer money to support two institutes. Our patients make no such distinction.

Best wishes for this important work.

Charles P. O'Brien, MD, PhD
Kenneth Appel Professor
Department of Psychiatry
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RSA PRESIDENT:
Peter M. Monti, Ph.D.
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May 19, 2009

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

I am writing on behalf of the 1,700 scientists and researchers who are members of the Research Society on Alcoholism (RSA) to encourage you to hold in abeyance any deliberations by the NIH Scientific Management Review Board (SMRB) concerning possible changes in the organizational structure of the National Institutes of Health until you have had the opportunity to determine whether such deliberations are prudent and in concert with President Obama's health policy objectives. In particular, we believe that the April 29th decision of the SMRB to discuss a possible merger of the National Institute of Alcohol Abuse and Alcoholism (NIAAA) and the National Institute of Drug Abuse (NIDA) was premature.

In RSA's view, a discussion about combining two important Institutes is not appropriate at this time because many of the NIH officials who would be directly responsible for this issue are not yet in place, let alone fully briefed on the ramifications of such a merger. The President has not yet named a Director of NIH or a permanent Director of NIAAA. RSA believes that it is axiomatic that the Director of NIH to be nominated by the President and confirmed by the Senate should have responsibility for tasking the SMRB to pursue specific issues, particularly those which could impact the fundamental structure of NIH.

Further, as a policy matter, RSA strongly opposes a merger of NIAAA and NIDA for numerous reasons including, inter alia:

1. There is no significant mandate of alcohol research that cannot be addressed within the present structure of NIH. NIAAA currently supports all areas of research relevant to alcohol use, alcohol-related problems, alcohol-related toxicity, and alcohol abuse and dependence. Furthermore, there are no meaningful barriers to collaborative efforts between NIAAA and NIDA (or other Institutes and Centers) on matters of addiction. Indeed, many

NIH initiatives undertaken since the NIH Reform Act of 2006 have enhanced collaboration among the Institutes.

2. NIAAA is one of the smallest Institutes at NIH, yet it has responsibility for one of the most significant public health problems—alcoholism and alcohol abuse. Merging NIAAA with NIDA will likely impede, not advance, NIAAA's critical research initiatives and mission.

3. NIAAA's emergence as an Institute brought the importance of alcohol-related health problems to national attention and signaled to researchers outside the community that alcohol research is an important public health endeavor and area of scientific inquiry. It has attracted the best and brightest investigators to the field. Merging the Institutes will almost certainly obfuscate that message to the detriment of the field of research.

4. Strategic planning and funding in support of alcohol research would likely be diluted and unfocused in a merged Institute. In addition, there are established ways for Institutes and Centers to promote trans-NIH research and scientific collaboration.

RSA endorses the President's efforts to reform the U.S. health care system by better managing chronic diseases, encouraging prevention and wellness initiatives, and promoting healthy lifestyles. It is beyond cavil that alcoholism and alcohol-related diseases extract a terrible toll on this country. Please find enclosed an RSA "white paper" entitled "*Impact of Alcoholism and Alcohol Induced Disease on America*" which demonstrates that alcoholism is a serious disease that affects the lives of millions of Americans, devastates families, compromises national preparedness, depresses economic vitality, and burdens the country's health care systems. It also documents that alcohol abuse and heavy drinking can be as much of a health care burden as alcohol dependence. RSA believes addressing alcoholism, alcohol abuse, and alcohol-related diseases in a thoughtful manner will improve the quality of care and reduce health care costs. RSA submits that NIAAA's critical efforts to address this serious health care issue should not be compromised by merging NIAAA and NIDA.

For the reasons articulated above, RSA respectfully urges you to defer consideration of NIH structure issues until the NIH hierarchy is in place and able to address the plethora of critical issues that must be carefully explored before any decision to initiate discussions is made. RSA stands ready to assist you and President Obama as you seek to improve this country's health care system and revitalize the NIH. We would particularly welcome the opportunity to work with you on alcohol-related matters related to these two issues.

Sincerely,

Peter M. Monti, Ph.D.
President
Research Society on Alcoholism

Impact of Alcoholism and Alcohol Induced Disease on America

January 12, 2009

Alcoholism is a serious disease that affects the lives of millions of Americans, devastates families, compromises national preparedness, depresses economic vitality, and burdens the country's health care systems. This disease touches virtually all Americans. More than half of all adults have a family history of alcoholism or problem drinking. Three in ten adults 18 years of age and over have had alcoholism and/or engaged in alcohol abuse at some point in their lives and their drinking will impact their families, communities, and society as a whole. Untreated addiction costs America $400 billion annually and recent research indicates that alcoholism and alcohol abuse alone cost the nation's economy approximately $185 billion each year. Fifteen percent of this amount is the cost of medical consequences and alcohol treatment; more than 70 percent is due to reduced, lost and forgone earnings; and the remainder is the cost of lost workforce productivity, accidents, violence, and premature death.[1]

This paper documents the deleterious impact of heavy drinking, alcohol abuse and alcoholism on the United States. As explained more fully below, heavy drinking (defined as having five or more drinks in a single day at least once a week for males, and 4 or more for females), contributes to illness in each of the top three causes of death: heart disease, cancer, and stroke. The Centers for Disease Control and Prevention (CDC) ranks alcohol as the third leading cause of preventable death in the United States.[2] According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA), 3 in 10 U.S. adults engage in at-risk drinking patterns and thus would benefit from counseling or a referral for further evaluation.[3]

The CDC also links excessive alcohol use, such as heavy drinking and binge drinking, to numerous immediate health risks that pose a menace not only to those consuming alcohol, but also to those around them including traffic fatalities, unintentional firearm injuries, domestic violence and child maltreatment, risky sexual behaviors, sexual assault, miscarriage and stillbirth, and a combination of physical and mental birth defects that last a lifetime.

Hypertension and Heart Disease

People who drink alcohol excessively have a one and a half to two times increased frequency of high blood pressure. The association between alcohol and high blood pressure is particularly clear when alcohol intake exceeds 5 drinks per day, and the prevalence of hypertension is doubled at 6 or more drinks per day. Among the risk factors for hypertension that have the potential to be modified, alcohol is second only to obesity in its observed contribution to the prevalence of hypertension in men. These findings have yet to be verified in women.[4] When managing hypertensive patients, however, relevant counseling can bring about a reduction in high blood pressure.

Numerous studies suggest that moderate alcohol consumption (no more than 2 drinks/day for men and 1 drink/day for women) helps protect against heart disease by raising HDL (good)

cholesterol and reducing plaque accumulations in the arteries. Alcohol also has a mild anti-coagulating effect, keeping platelets from clumping together to form clots. Both actions can reduce the risk of heart attack but exactly how alcohol influences either one still remains unclear. On the other hand, consumption of more than three drinks a day has a direct toxic effect on the heart. Heavy drinking, particularly over time, can damage the heart and lead to high blood pressure, alcoholic cardiomyopathy, congestive heart failure, and hemorrhagic stroke. Heavy drinking also impairs fat metabolism and raises triglyceride levels.

CANCER AND STROKE

According to the NIAAA, considerable evidence suggests a connection between heavy alcohol consumption and increased risk for cancer, with an estimated 2 to 4 percent of all cancer cases thought to be caused either directly or indirectly by alcohol.[5] A strong association exists between alcohol use and cancers of the esophagus, pharynx, and mouth, whereas a more controversial association links alcohol with breast cancer. Together, these cancers kill more than 125,000 people annually in the United States.[6]

ALCOHOL'S EFFECTS DURING PRENATAL DEVELOPMENT

Data from the CDC indicate that 12 percent of pregnant women drink alcohol. Approximately one in 100 babies is born with one of the Fetal Alcohol Spectrum Disorders (FASD). Alcohol's effects on the developing brain are life-long and impact many behaviors including motor and sensory skills, social skills, and learning abilities. As individuals with FASD grow up, they are at greater risk for a variety of secondary disabilities including other psychiatric problems, illicit drug use, delinquent or criminal behavior, precocious or risky sexual activity, and academic failure. There is no known stage of pregnancy or quantity of alcohol consumption that is safe during pregnancy.[7] Current research on the effects of early alcohol exposure include not only prevention but also early life interventions, establishing and implementing more effective diagnostic tools, and understanding the mechanisms underlying the tragic outcomes associated with FASD.

TRAUMA AND BURNS

Alcohol plays a significant role in trauma by increasing both the likelihood and severity of injury. Alcohol abusers are more likely than sober persons to be involved in a trauma event – i.e. heavy drinkers have a higher risk for accidents than non-drinkers.[8] Given similar circumstances, a drinker is also likely to be hurt more seriously than a non-drinker. Moreover, an estimated 27 percent of all trauma patients treated in emergency departments and hospitals are candidates for a brief alcohol intervention.[9]

Alcohol exposure can also alter inflammatory responses and immune function and this can be exacerbated if there is an existing or concurrent injury. Research suggests that chronic heavy drinking depresses estrogen levels, nullifying estrogen's beneficial effects on the immune system and weakening a woman's ability to fight infections and tumors. Additionally, some research suggests that this detrimental effect may be compounded by an alcohol-induced elevation in steroidal hormones, known as glucocorticoids, which suppress immune responses in both men and women.[10]

DOMESTIC VIOLENCE AND CRIMES

The relationship between alcohol or other substance abuse and domestic violence is complicated. Frequently either the perpetrator, the victim or both have been using alcohol heavily. According to the National Woman Abuse Prevention Project, some abusers rely on substance use (and abuse) as an excuse for becoming violent. Alcohol allows the abuser to "justify" abusive behavior. While an abuser's use of alcohol may have an effect on the severity of the abuse or the ease with which the abuser can justify their actions, an abuser does not become violent "because" drinking causes them to lose control of their temper.

According to the 1998 Department of Justice Report on Alcohol and Crime, alcohol abuse was a factor in 40 percent of violent crimes committed in the United States. About 3 million violent crimes occur each year in which victims perceive the offender to have been drinking at the time of the offense. Among those victims who provided information about the offender's use of alcohol, about 35 percent of the victimizations involved an offender who had been drinking. About two-thirds of the alcohol-involved crimes were characterized as simple assaults. Two-thirds of victims who suffered violence by an intimate (a current or former spouse, boyfriend, or girlfriend) reported that alcohol had been a factor. Among spouse victims, 3 out of 4 incidents were reported to have involved an offender who had been drinking. By contrast, an estimated 31 percent of stranger victimizations where the victim could determine the absence or presence of alcohol was perceived to be alcohol-related.

AUTOMOBILE RELATED ACCIDENTS

In 2006, 13,470 people were killed in alcohol-impaired-driving crashes. These alcohol-impaired-driving fatalities accounted for 32 percent of the total motor vehicle traffic fatalities in the United States; and represented an average of one alcohol-impaired-driving fatality every 39 minutes. Traffic fatalities in alcohol-impaired-driving crashes fell by 0.8 percent, from 13,582 in 2005 to 13,470 in 2006, almost the same as the 13,451 alcohol-impaired-driving fatalities reported in 1996. Drivers are considered to be alcohol-impaired when their blood alcohol concentration (BAC) is .08 grams per deciliter (g/dL) or higher.[11]

In 2006, 1,794 children age 14 and younger were killed in motor vehicle crashes in the US. Of those 1,794 fatalities, 306 (17 percent) occurred in alcohol-impaired driving crashes. Children riding in vehicles with drivers who had a BAC level of .08 or higher accounted for half (153) of these deaths. Another 45 children age 14 and younger who were killed in traffic crashes in 2006, were pedestrians or pedalcyclists who were struck by drivers with a BAC of .08 or higher.[11]

UNDERAGE DRINKING

According to the NIAAA, approximately 5,000 people under the age of 21 die as a result of underage drinking each year; this includes about 1,900 deaths from motor vehicle crashes, 1,600 as a result of homicides, 300 from suicide, as well as hundreds from other injuries such as falls, burns, and drownings.[12-16]

The NIAAA, along with the National Institute on Drug Abuse (NIDA), and the Substance

Abuse & Mental Health Services Administration (SAMSHA), have conducted research that demonstrates that substance abuse is particularly problematic in younger adolescents because it is the time when individuals are most vulnerable to addiction. According to the CDC, people aged 12 to 20 years drink almost 20 percent of all alcohol consumed in the United States. The NIAAA's *National Epidemiologic Survey on Alcohol-Related Conditions* (NESARC) found that 18 million Americans (8.5 percent of the population age 18 and older) suffer from alcohol use disorders (AUD), and only 7.1 percent of these individuals have received any treatment for their AUD in the past year.

NIAAA's NESARC survey sampled across the adult lifespan to allow researchers to identify how the emergence and progression of drinking behavior are influenced by changes in biology, psychology, and exposure to social and environmental inputs over a person's lifetime. Scientists at NIH are supporting research to promulgate pre-emptive care for fetuses, early childhood, and adolescents because children who engage in early alcohol use also typically display a wide range of adverse behavioral outcomes such as teenage pregnancy, delinquency, other substance use problems, and poor school achievement.

In 2006, 30 percent of high school seniors reported exposure to a drinking or drugged driver in the past 2 weeks, down from 35 percent in 2001. Exposure was demonstrated to be widespread as defined by demographic characteristics (population density, region of the country, socioeconomic status, race/ethnicity, and family structure). Individual lifestyle factors (religiosity, grade point average, truancy, frequency of evenings out for fun, and hours of work) showed considerable association with the outcome behaviors.[17]

SPECIAL POPULATIONS: ACTIVE MILITARY AND VETERANS

The prevalence of heavy drinking is higher in the military population (16.1 percent) than in a similar age and gender civilian population (12.9 percent). About one in four Marines (25.4 percent) and Army soldiers (24.5 percent) engages in heavy drinking; such a high prevalence of heavy alcohol use may be cause for concern about military readiness. Furthermore, the Army showed an increasing pattern of heavy drinking from 2002 to 2005. According to the Department of Defense's (DoD) *2005 Survey of Health Related Behaviors among Active Duty Military Personnel*, these patterns of alcohol abuse, which are often acquired in the military, frequently persist after discharge and are associated with the high rate of alcohol-related health disorders in the veteran population

COSTS TO BUSINESSES AND ECONOMIC PRODUCTIVITY

Employee alcohol use causes a variety of problems. It reduces productivity, impairs job performance, increases health care costs and can threaten public safety. Because 85 percent of heavy drinkers work, employers who aggressively address this problem can improve their employees' health while improving company performance. The federal government estimates that 8.9 percent of full-time workers (12.7 million people) have drinking problems. Alcohol costs American business an estimated $134 billion in productivity losses, mostly due to missed work; 65.3 percent of this cost was caused by alcohol-related illness, 27.2 percent due to premature death, and 7.5 percent to crime. People with alcoholism use twice as much sick leave as other employees. Individuals with alcoholism are also five times more likely to file workmen's

compensation claims and they are more likely to cause injuries to themselves or others while on the job.[18-24]

COSTS TO HEALTH PLANS

About 80 percent of people with alcohol problems work, yet fewer than 25 percent of those who need treatment get it. Untreated alcohol problems cost employers in several ways--greater health care expenses for injuries and illnesses, higher absenteeism, lower productivity, and more workers' compensation and disability claims. Research has shown that alcoholism treatment that is tailored to an individual's needs could be cost-effective for employers. Treatment substantially reduces drinking among people with alcoholism, and 40 to 60 percent of those treated for addiction remain abstinent after a year. By providing comprehensive health benefits that cover treatment for alcohol use disorders, employers can reduce their health care and personnel costs as well as contribute to employees' well-being and productivity.[25]

CONCLUSION

While the high rates of use and abuse of alcohol are devastating problems of national importance, the good news is that this nation is poised to capitalize on unprecedented opportunities in alcohol research and prevention. These opportunities must be seized. Scientists are exploring new and exciting ways to prevent alcohol-associated accidents and violence and more prevention trials are developing methods to address problem alcohol use. Medications development is proceeding faster than anytime in the past 50 years, with many new compounds being developed and tested. Furthermore, researchers have identified discrete regions of the human genome that contribute to the inheritance of alcoholism. Improved genetic research will accelerate the rational design of medications to treat alcoholism and also improve understanding of the interaction and importance of heredity and environment in the development of alcoholism.

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November 5, 2009

Mr. Norman Augustine (Chair)
Retired Chairman and CEO
Scientific Management Review Board, OD, NIH
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dear Mr. Augustine,

I am writing to you with respect to the potential merger of the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Addiction. On behalf of TASC, a statewide nonprofit agency in Illinois that serves almost 30,000 clients a year, **I support this merger.**

Since 1976, TASC has helped people with alcohol and drug health conditions get the treatment and other services they need to begin sustained recovery. We conduct clinical assessments, place clients into community-based treatment programs, and case manage individuals referred to us by courts, prisons, and foster care. We rely on and advocate for science-based, research-based, and evidence-based practices in community treatment and in the public systems that interface with it.

The strongest rationale for my support of a NIDA/NIAAA merger is that thousands of people come to us each year with substance use histories that include both licit and illicit substances. This is the rule, not the exception. While it may have made sense at some point to separate dedicated research and funding to alcohol and drugs respectively, the reality faced by the criminal justice system today simply does not require or benefit from such a separation.

The medical consequences of using drugs and alcohol are closely related. While specific substances of abuse have some unique characteristics, their effects have enough in common that there is no basis in practice for separating them in research. Further, we know that alcohol use is a confounding factor for recovery from drug use, that drug use is a confounding factor in recovery from alcoholism, and that continued tobacco use is a confounding factor in all recovery.

Similarly, there is no scientific basis for separating research on licit and illicit substances. Public policy responses may be different because of a substance's legal status, but as the treatment field and justice system move toward research- and evidence-based practices, science and evidence should drive smart policy instead of the reverse.

The issue for the justice system is having adequate research to articulate the effects of alcohol and other drugs on the brain, on judgment and therefore culpability, on behavior and then on treatment, relapse and recovery. We need integrated research to drive our policy and practice decisions in these cases. These questions have real world implications for child safety and reunification, for prevention and recovery, and for reducing crime and recidivism.

The next generation of research in alcohol and drug abuse and recovery needs to help us understand why particular interventions work, when they work, and with whom they are effective. Combining NIDA and NIAAA would help pave the way for better and more appropriate services within a criminal justice context at a faster pace and to a greater degree. Merging the institutes will move addiction research forward by better facilitating focus on areas that currently represent gaps in our knowledge and understanding.

Like the impressive research each institute has undertaken separately, and like the contribution each institute has made toward understanding drug use and alcohol use separately, **merging NIDA and NIAAA has the potential to achieve quantum leaps in our understanding of substance abuse and addiction as they truly occur.** It will consolidate and synthesize what we know, and it will shine a light on the areas that have been neglected because they reside somewhere between or otherwise outside of each research institute and its mission.

Finally, if this merger does take place, I strongly advocate that overall funding not be diminished. The unification of these institutes should not be viewed as a means of streamlining to diminish dollars, but rather as a way to better invest and leverage them. Bringing an end to the artificial separation with adequate funding will bring more fruit to bear.

Thank you for allowing me to share my views in this important matter.

Sincerely,

Pamela F. Rodriguez
President

American Psychiatric Association

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September 22, 2009

Norman Augustine
Chair, Scientific Management Review Board
OD/NIH Bldg 1 Rm 103
9000 Rockville Pike
Bethesda, MD 20892

Dear Mr. Augustine:

On behalf of the American Psychiatric Association (APA), a national medical specialty society whose 38,000 physician members specialize in diagnosis, treatment, prevention and research of mental illnesses including substance use disorders, I welcome the opportunity to comment on the Scientific Management Review Board's (SMRB) deliberations regarding the possibility of a merger between the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA).

From a scientific perspective, a merger between NIAAA and NIDA makes sense. The Institute of Medicine's 2006 Report "Genes, Behavior and the Social Environment: Moving Beyond the Nature/Nurture Debate" made clear that translational research was the scientific pathway for addiction research and improvements in treatment. Such translational research could be greatly fostered and enhanced by a NIAAA-NIDA merger. The current division has conceptual limitations-- it does not even represent a break between licit and illicit drugs, given that studies of nicotine are generally supported by NIDA. Given commonalities in areas such as biology, culture, and frequent use of multiple substances, there are logical reasons to have a single Institute devoted to substance use disorders. The field of addictions research and medicine - and ultimately patients - would be well served if there is greater dialogue and work between current research groups. While dialogue already occurs to some extent, it seems likely there would be eventual enhancement and increased productivity in addictions research if such a merger occurred.

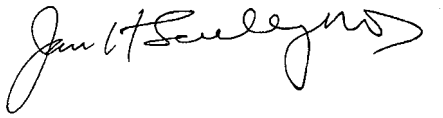
From a practical perspective, a NIAAA-NIDA merger would not be without concern. Extramural and intramural research funding in these areas is already far lower than their relative public health importance and should not be jeopardized. Differences in social aspects of alcohol and nicotine versus illicit drug use are also worth noting and attention should be given to maintaining appropriate research efforts to improve prevention and treatment efforts in these different social environments. While we recognize that NIH cannot guarantee

there will not be budgetary cuts, there are serious concerns about the potential size of any budgetary reduction that are justified on the basis of administrative reductions, since the degree of administrative duplication is at times overestimated.

While the operationalization of a merger does present challenges that must be carefully monitored and addressed, including the organizational challenges of combining two Institutes of disparate sizes, these challenges and concerns should not stand in the way of scientific advancement. The science of addiction research, the potential for improved treatments, and the promise for improving the lives of patients and their families, leads the APA to support a proposed merger between NIAAA and NIDA.

The American Psychiatric Association appreciates this opportunity to provide input on this topic to the Scientific Management Review Board. Please contact APA's Director of Research, Darrel A. Regier, M.D., M.P.H., dregier@psych.org if the APA can be of further assistance as the SMRB's discussions progress.

Sincerely,



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Testimony of Lynn Hernandez, Ph. D.
Title: Postdoctoral Research Fellow

My name is Lynn Hernandez and I am a postdoctoral research fellow at Brown University's Center for Alcohol and Addiction Studies. I would like to thank the members of the Scientific Resource Management Board for giving me the opportunity to share my thoughts and feelings regarding the possible merger of NIAAA and NIDA. I am here today to not only deliver my testimony but to also speak on behalf of the current class of both NIAAA and NIDA funded postdoctoral fellows who strongly believe that NIAAA should remain a distinct Institute focused on the scientific inquiry of the etiology, treatment, and public health consequences of alcohol use.

I will begin by telling you a little bit about my own personal journey through the educational pipeline, one that ended with me actively and passionately pursuing a career in alcohol research. At the start of my graduate school experience, I had a vague idea of the type of research I wanted to pursue and therefore entered a state of research identity moratorium. In search of a research niche, I engaged in a diverse set of training experiences. These experiences included research with sexually abused children, research with parents of conduct disordered children, and development of couples relationship enhancement programs. Not being fully satisfied or feeling the passion to actively continue pursing any of these areas of research, I sought advice from a mentor who told me "search for and do whatever keeps that fire in your belly burning." I decided to continue exploring different research options and became involved with a research group that developed and examined the efficacy of community-based interventions for adolescents exhibiting problem behaviors, behaviors which included alcohol abuse. I began my training with them by conducting comprehensive assessments with adolescents engaging in problematic drinking. To my surprise, the challenges that this new population presented sparked and kept the fire burning. This newly discovered interest in alcohol research got me excited to pursue other research activities and experiences related to alcohol abuse. Training as a developmental psychologist, I began to learn about the distinct complexities that existed in examining alcohol use and drug use trajectories among adolescent populations, and also became aware of the distinct challenges in addressing these two behaviors. For instance, alcohol use during adolescence is a developmentally normative behavior, and adolescents drink within the context of a society where alcohol is widely available, aggressively promoted, and where alcohol use among adults is normative. Therefore, addressing alcohol use in adolescents from a "responsible drinking" and harm reduction approach seems appropriate. Yet, drug use during adolescence occurs in the context of other problems in the life course and requires an approach that promotes abstinence. This new understanding lead to my pursuit of knowledge on the developmental mechanisms underlying alcohol use among adolescents, an endeavor which was supported by NIAAA. It was through this support received from NIAAA that I was allowed to explore and passionately commit to an alcohol research career.

After graduating with a doctoral degree in tow, I was fortunate to receive further training in alcohol etiology and treatment development by obtaining a postdoctoral fellowship at the Center for Alcohol and Addictions Studies. My research at Brown has focused on the development of culturally appropriate alcohol interventions for Hispanic/Latino adolescents. Once again, this research has been

supported by NIAAA, and most recently by an NIAAA-funded diversity supplement to further my training and expert knowledge development in this area of alcohol research.

The point of describing my educational trajectory is not to stress the distinct mechanisms underlying alcohol use and drug use among adolescents and Hispanic/Latinos, but to emphasize the importance of having two distinct institutes for the current and future training of young investigators. As I myself experienced, young investigators go through a phase of research identity exploration. We experiment with different research options before arriving at the one we would like to dedicate our research careers to. These choices are influenced and shaped by the support available to us and by our beliefs in our capacity to negotiate what can be complex and daunting funding systems. For those of us who chose to become alcohol researchers, having a distinct institute to house our research ideas and interests encourages us to continue pursuing knowledge in alcohol research and allows us to disseminate this knowledge to further the advancement of alcohol research. Losing an independent institute devoted to research on alcohol abuse and alcoholism would not only deter the recruitment of new researchers to the field but also discourage those in the process of developing expert knowledge, thus disrupting the educational pipeline. As young investigators, we represent the new generation of researchers; therefore, without a distinct institute to support our alcohol specific ideas, the alcohol research field would suffer from a lack of diverse and innovative approaches to the scientific inquiry of alcohol.

Therefore, speaking for myself and on behalf of my colleagues, we believe that a merger of NIAAA with NIDA would harm alcohol research efforts rather than advance the field. It would do so by hindering the recruitment and retention of promising new alcohol investigators, thus doing a disservice to the future of alcohol research.

Thank you for allowing me to testify before your committee.

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November 13, 2009

Scientific Management Review Board
National Institute of Health

Dear Committee Members,

First - I would like to thank you for the opportunity to speak with you today and thank you for the time and effort that you have devoted to this issue. My name is Susan Barron - I am faculty in the Psychology Department at the University of Kentucky. I am on the Kentucky Task Force for Fetal Alcohol Spectrum Disorders, a former President of the Fetal Alcohol Syndrome Study Group and I currently serving on the Board of Directors for the Research Society on Alcoholism.

In my limited time today, I would like to make a couple of points regarding some of my concerns and why I strongly oppose the idea of a merger between NIAAA and NIDA.

First, I would like to speak to my area of research - studying the effects of prenatal alcohol exposure. Fetal Alcohol Spectrum Disorders represents the largest non-genetic cause of mental retardation (with an estimated incidence of 1 per 1000 birth for a full FAS and the number of children significantly affected by alcohol being closer to 1 in 100. The NIAAA supports a broad range of FASD research ranging from work in molecular biology through to psychological approaches; Included are such areas as genetics, neuroscience, epidemiology, nutrition, immunology, endocrinology, organ damage, prevention, behavioral interventions, and international collaborations to name a few.

This systems approach to the study of FASD by the NIAAA provides tremendous opportunities for enhanced communication and collaboration across many diverse research areas. This makes the NIAAA critical - not just for FASD research but for many of the questions that we examine in the alcohol field. What would happen if NIDA and NIAAA were merged into some form of addiction institute? Many issues related to FASD would not fit in this institute. Would these be scattered across other NIH institutes or perhaps vanish entirely? The NIAAA allows for this systems approach - and this has significant benefits, I believe, for the science and for helping individuals and families living with the effects of prenatal alcohol exposure.

2. Alcohol is the only legal, socially acceptable, recreational drug and so research on alcohol requires a different approach than research on other drugs of abuse.

Alcohol use disorders (AUDs) arise in the context of widespread, healthy, social drinking. More than 120 million Americans use alcohol recreationally yet never develop an alcohol use disorder.

Alcohol can have clear social and health benefits, including such things as a reduced risk for heart disease and stroke. In contrast, the recreational use of inhalants, nicotine, prescription drugs or illegal drugs is not socially acceptable or medically advisable.

One important goal of alcohol research is to inform public policy and education to help limit drinking to safe levels in healthy adults and to encourage abstinence during pregnancy and before the age of 21. Abstinence or prohibition, the fundamental model of prevention for most drugs of abuse, does not work with alcohol. The social use of alcohol is part of our society and culture. The existence of NIAAA is an acknowledgement that there are different public health issues for alcohol than for other drugs. The

merger of NIAAA and NIDA would make the public health message of each institute less clear and could result in confusion to the public.

3. Finally, I worry for the future. The existence of the NIAAA and its support of students and junior scientists has brought many extremely bright, innovative junior investigators into alcohol research. I became involved in alcohol work as a graduate student and the support that this institute provides in so many ways is a contributing factor for many of us that have had a career studying the effects of alcohol. I worry about the message sent to junior faculty and new graduate students if a merger was to occur. The potential cost due to the loss of our many future scientists in the field of alcohol research is not something that we can calculate easily yet we know that junior investigators, postdocs and graduate students are anxious about this.

So in conclusion, I want to make sure that my message to you is clear. I believe that what we stand to lose through the merger of NIAAA and NIDA is far more than what we stand to gain. There would be a significant period of disruption and confusion, we would lose the integrative nature that the NIAAA provides to address some of the complex issues surrounding alcohol and we could lose a future generation of scientists interested in this field. What we stand to gain through merger can be accomplished through alternative approaches, including enhanced collaboration between NIAAA and NIDA as well as with other related agencies.

Again, I would like to thank you for this opportunity.
Sincerely,

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Associate Professor

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