NIH Scientific Management Review Board

Needs in Public Health: Preventing Risky Use and Treating Addiction Panel Presentation I

John T. Carnevale, Ph.D.
Carnevale Associates, LLC
John@Carnevaleassociates.com

May 18, 2010

Please let me begin by expressing my appreciation to appear before you today. By way of background, I am a public finance economist who has been involved in formulating federal national drug control policy and its supporting budget since 1986. Many of those years were spent at the level of Executive Office of the President—working at the Office of Management and Budget and at the White House Office of Drug Control Policy (the ONDCP) from 1989 to 2000.

Last September, I spoke before the Substance Use, Abuse, and Addiction Working Group (I will refer to it today as the Working Group) and asked them to perceive my role as representing one of those "inside the beltway" bureaucrat or Hill staff types that any proposed reorganization would eventually encounter. I would like to continue to remain in this role for purposes of today's discussion.

With regard to the issue before us today, let's start with what we know:

- The Working Group is charged with recommending to the full SMRB whether an organizational change could further optimize research into substance abuse, use, and addiction. This essentially boils down to the question of whether science could benefit from some type of merger of two institutes—NIDA and NIAAA.

- I understand that the Working Group does agree that maintaining the status quo is not desirable for optimizing NIH's mission into this area, but it has yet to reach agreement as to the best reorganizational option.

- I further understand that Working Group is now considering three types of reorganizations:

    1. Functional reorganization of all research programs with a relevant scientific focus (including, but not limited to, NIAAA and NIDA) or

    2. Structural reorganization—that is, a merger of NIDA and NIAAA into a single institute focused on alcohol and drug abuse and addiction, or

3. Hybrid reorganization—that is, a combination of a functional and a structural reorganization.

Indeed, one diagram presented in Dr. Roper's March 10 power point summary identifies eight different options within the full spectrum of the structural and functional reorganizations. Five represent functional reorganizational options; one is about maintaining the status quo, and two others are really one and the same in my mind: creating a single entity by merging NIAAA and NIAAA (which to me is the equivalent of creating a new institute.) I view this list as being much too long and complicated and could serve to prevent seeing the forest for the trees (especially when we overlay the hybrid reorganization option).

From my perspective as an economist, myriad reorganizational options, for example, between a functional versus a structural reorganization, are dubious. All mergers are functional from some perspective. I don't really know what it means to merge organizations on some non-functional basis – even if the basis is merely to exercise common control. Structure emerges to support function. If structure doesn't support function, then it's just an artifact.

With this perspective in mind, there is actually only one "structural" selection to be made: Retain the status quo (keep NIDA and NIAAA separate), or merge them while maintaining a strict alcohol and drug focus, or, combine them into one Institute with some broader, yet to-be-determined "scientific" focus.

As an aside, I have another concern about the concept of a "functional" merger. Regardless of how it is eventually defined, a functional merger will in my opinion serve to confuse the appropriations process. For example, appropriating funds for research according to a "relevant scientific purpose" or a "linkage with a cross-cutting blueprint" will confuse (rather than clarify) funding options. Moreover, the notion of management by a "Single Council" or according to "Clustered Functions" adds to the confusion.

Is it possible that so many reorganization options are being considered because many individuals quietly favor the status quo and are intent on defeating the idea of a merger by confiscation rather than clarity? I can only speak from my own perspective, but I find these various reorganization concepts to be subjective, variable, politically sensitive, and not specific enough to assist appropriators in either understanding, much less prioritizing how best to spend the taxpayers' money. Perhaps the most valuable guidance I can offer is this: The tougher the fiscal environment, the more appropriators want, and need, clear boundaries.

Now, to get back to the fundamental issue on the table, I favor creating a new Institute that combines or merges NIAAA and NIDA, but on the condition that the new Institute's mission be clearly defined and maintained. Such a merger, in other words, must not deteriorate into what is commonly referred to as "mission creep." An example of "mission creep" would be as follows: *Since NIDA and NIAAA are combined, why not target all behaviors related to the function of brain reward? Let's solve the addictions puzzle once and for all. Why stop at alcohol, tobacco, and illicit drugs, when gambling, sex, exercise, shopping, and food addiction also share the same biology? With an expansion of research priorities to explore, we would expect an expansion of resources or else face a reduction in the new Institute's core mission.*

My experience tells me that this kind of gradual "mission creep" could easily dilute the chances for securing funding for what is clearly an urgent and singular priority: drug and alcohol research. In the long-run, it could even place the alcohol and drug research priority squarely on the budget chopping block.

My concerns are based on first-hand experience with monitoring the Federal budget for the Safe and Drug Free Schools Program. When the program was first authorized in the 1980s, it was known as "The Drug Free Schools" Program and one hundred percent of its resources targeted drug prevention. Then, because of isolated yet serious, incidents of school violence, the program was reauthorized to include the word "safe" in its mission. What was once a highly functional drug prevention program now had a much larger and more generalized mission; appropriators were *required* to satisfy the additional interests of those concerned with the far broader nexus of drugs *and* violence. The appropriators' obligation--a nearly impossible challenge--was to slice a much larger and more "generally targeted" piece of the budget pie to address not only school drug use, but also school violence, and eventually, all youth violence in general.

As it turned out, the identity of the program became diluted and vague and funding levels could never quite keep up with the scope of the expanded "safe *and* drug-free" mission. Last year, the Safe and Drug Schools Program was deemed ineffective and terminated. I do not want this story to be told someday about the merger of NIDA and NIAAA.

This now brings me to the thorny issue of naming the merged or combined organization. The proposed "Institute on Addictions" invites too much "mission creep." What makes good practical sense, from both an appropriations and research perspective, is to retain as the "crown jewel" of the new Institute, a drug and alcohol focused mission. Perhaps something more simple and straight-forward like: The National Institute on Drugs and Alcohol Abuse. (Parenthetically, I bet this is a very sensitive bureaucratic issue behind closed doors.)

I do have a few other policy and program concerns:

- One concern is workforce related: Those of us at the national drug policy level have worked very hard since the late eighties to expand the pool of researchers, particularly in the area of illicit drug abuse, to help inform our national drug policies. A decade ago, I would have opposed the merger simply because those of us in policy/budget formulation fought hard to expand this area of research and wanted to protect our turf. Today, after seeing the extraordinary advances in the science of drug addiction, I now believe that continuing to silo drugs and alcohol research within NIH may reduce career opportunities for researchers.

- Another concern is behavioral-health related: I am concerned that the merger could push drug and alcohol research more toward the neurobiological side of science and less toward furthering our understanding of the behavioral health aspects of abuse and addiction. Our nation's public policy requires more understanding of behavioral health issues so that the so-called science-to-service effort can be strengthened.

- A final concern is funding: A merged Institute will presumably offer some savings in Administrative costs. I suspect that such savings will be meager, but even meager savings could look like raw meat to those at the Office of Management and Budget and in Congress. I would hope that arguments are being considered now about how best to use any new funds raised by the merger to help with the integration of alcohol and drug research.

This concludes my comments. I again wish to thank the Scientific Management Review Board for allowing me to participate in this discussion.

NAEVR
National Alliance For
Eye And Vision Research
Serving as Friends of the National Eye Institute

12300 Twinbrook Parkway
Suite 250
Rockville MD 20852
240-221-2905; www.eyeresearch.org

Public Statement Regarding Organizational Change/Merging Institutes
NAEVR Executive Director James Jorkasky
Scientific Management Review Board Meeting
May 18, 2010

Good afternoon. I am James Jorkasky, Executive Director of the National Alliance for Eye and Vision Research, or NAEVR, which serves as the privately funded ""Friends of the National Eye Institute (NEI)." I am providing these brief public comments about the potential broader impact of merging Institutes/Centers (I/Cs) within the NIH, as the SMRB's actions regarding a merger of the Drug and Alcohol Institutes could have far-reaching implications.

For the past year, I have attended the SMRB meetings and have listened intently and respectfully to all of the points that have been made, both pro and con. I am truly humbled by the thoughtful comments already expressed today by the panelists.

As background, NAEVR has long opposed the concept of "clustering" I/C budgets:

- Going back to the 2001 timeframe, NAEVR opposed the proposal by former NIH Director Harold Varmus to cluster the budgets/programs of the 27 I/Cs into six units, including a "Brain Institute," which would have incorporated the NEI.

- From 2005-2006, NAEVR opposed the budget cluster proposal within draft NIH reform legislation. In my extensive Capitol Hill visits to oppose this provision in the draft bill, I was initially met with support for clusters, based on an assumption of greater efficiency and scientific interaction. But after I discussed potential implications for the actual research involved, most offices expressed reservations—or, as Chairman Augustine has said, "this is more complicated than we thought." The fact that the cluster proposal was stripped from the final version of the bill, and that the SMRB was charged to comprehensively study the far-reaching scientific implications of such organizational change, has spoken volumes.

Having established this background, I offer the following observations:

- At the SMRB's April 27-28, 2009, inaugural meeting, Dr. Varmus spoke and recognized within his comments that numerous steps had already been taken through the 2006 reauthorization and administratively within NIH to foster trans-Institute research, meeting many of the goals of his cluster proposal.

- At the same meeting, immediate-past NIH Director Dr. Elias Zerhouni spoke passionately about many aspects of the NIH that he would like to see changed. Merging or clustering I/Cs was not one of those priorities.

- In public comments at past SMRB meetings, including those immediately preceding me by Dr. Sanyal, researchers into liver function expressed concern that such research could "go away" or be minimized in a merged Institute. I would like to expand on this concern by providing a similar example from the vision space.

This past year, the National Eye Institute celebrated its 40th anniversary as a free-standing Institute. Prior to 1968, vision research was conducted in the then-National Institute of Neurological Diseases and Blindness (NINDB), accounting for less than 20 percent of the Institute's budget. In just the past couple of weeks, for example, NEI has released results from four major studies on visual impairment and eye disease, relating to both retinal, or "back of the eye" research, and corneal, or "front of the eye" research.

The concept of clustering I/Cs into a "Brain Institute," as Dr. Varmus proposed, may have initially sounded rational, based on the assumption that all neurological research is related. However, when we started to look at the potential implications for the actual research involved, we were alarmed. For example:

- Although 50 percent of NEI-funded research relates to the "front of the eye," it would only account for 7 percent of a total "Brain" cluster budget. Future funding for this research could be jeopardized, including that into corneal diseases, cataracts, and refractive errors that affect millions of Americans and cost tens of billions of dollars, with devastating consequences for public health, productivity, and quality of life.

- If "front of the eye" research were not adequately funded, the vision community could permanently lose key investigators. Eye researchers and clinicians are uniquely qualified to understand and treat eye disease, since neurologists do not necessarily have an understanding of corneal disease or cataract.

In closing, I know from this morning's discussion that the SMRB will carefully weigh what could be the consequences for a merged Drug and Alcohol Institute in terms of the actual research priorities that will be funded.

Thank you.

Research Society on Alcoholism

Phone: 512-454-0022 E-mail: debbyrsa@sbcglobal.net Fax: 512-454-0812 Webpage: www.RSoA.org
7801 N. Lamar Blvd., Suite D-89, Austin, Texas 78752-1038

RSA PRESIDENT:
Sara Jo Nixon Ph.D.
Department of Psychiatry, University of Florida
P.O. Box 100256, Gainesville, FL 32610-0256
352-392-3681 sjnixon@psychiatry.ufl.edu

March 26, 2010

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

Dear Dr. Roper:

On behalf of the over 1,700 scientists, associates, and researchers represented by the Research Society on Alcoholism (RSA), we have frequently expressed our objections to a proposed merger between the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and National Institute on Drug Abuse (NIDA). RSA deeply appreciates the interest and attentiveness which you have paid to our concerns.

RSA has monitored SUAA's deliberations closely and it occurred to us that the views of the scientists and researchers who are "on the ground" conducting critical research may not have been fully aired.

To address this issue, RSA recently conducted a poll of its members over a two-day period in order to gauge the sentiment of its members about the potential merger. The survey asked whether the respondents agreed with or opposed the following resolution:

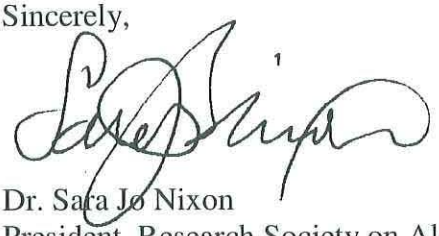
> "RSA strongly opposes any structural reorganization at NIH that results in the elimination of NIAAA as an independent Institute dedicated to all aspects of alcohol research. Moreover, RSA strongly supports the study of a functional reorganization of basic and clinical research across NIH Institutes to better address commonalities in alcoholism, substance abuse, obesity, gambling, and their co-morbid mental health disorders."

The results showed overwhelming opposition to the elimination of NIAAA as an independent Institute—597 respondents supported the proposition while only 18 opposed it, a 97 percent majority. This same majority, however, also endorsed a study of a functional reorganization of basic and clinical research across NIH Institutes.

We appreciate your diligent work to fully deliberate and review all aspects and potential outcomes of this important matter.

RSA stands ready to assist you and the SUAA Working Group as you work through the remainder of this process.

Sincerely,



Dr. Sara Jo Nixon
President, Research Society on Alcoholism

From:	jean public
To:	jennifer.spaeth@mail.nih.gov; SMRB (NIH\OD); americanvoices@mail.house.gov; comments@whitehouse.gov; info@starmagazine.com; info@taxpayer.net; media@cagw.org
Cc:	info@theteaparty.org
Subject:	public comment on fedeeral register Fw: wy are you allowing a committee to go to clearwater beach resort for their meeting
Date:	Monday, April 26, 2010 11:37:50 AM

why are yuo allowing the out of control spending of one of the committees going to clearwater beach to a beach resort for an alleged "meeting". why cant they meet via computer software as our president has done ans has requested thqt committees do? why are you allowing such out of control spending to hurt american taxpayers. why cant you stay in your own offices to have the meeting. you all have computers to meet with. this out of control spending by nih is compeltely offensive. cut costs please.
jean public 8 winterberry court whitehouse station nj 08889

> why are yuo burdening the taxpayers like this?
>
> [Federal Register: April 26, 2010 (Volume 75, Number 79)]
> [Notices]
> [Page 21642-21643]
> From the Federal Register Online via GPO Access [wais.access.gpo.gov]
> [DOCID:fr26ap10-70]
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> DEPARTMENT OF HEALTH AND HUMAN SERVICES
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> National Institutes of Health
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> Office of the Director, National Institutes of Health; Notice of Meeting
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> Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Scientific Management Review Board.
> The NIH Reform Act of 2006 (Pub. L. 109-482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.
> The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.
>
> Name of Committee: Scientific Management Review Board.
> Date: May 18-19, 2010.

Time: May 18, 2010, 8 a.m. to 5 p.m.

Agenda: Presentation and discussion will include updates from two SMRB Working Groups, the Substance Use, Abuse and Addiction group and the Intramural Research Program group. Participants will include both scientific experts and community stakeholders. Additional time will be allotted for presentation and discussion of each Working Group's draft recommendations to date. Any supporting documentation for this meeting, including the agenda, will be available at http://smrb.od.nih.gov. Sign up for public comment will begin at approximately 7 a.m. on both May 18 and 19 and will be restricted to one sign in per person. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the contact person's address below.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Time: May 19, 2010, 8 a.m. to 5 p.m.

Agenda: Continuation of May 18th meeting.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Lyric Jorgenson, Health Sciences Policy Analyst, Office of Science Policy, Office of the Director, NIH, National Institutes of Health, Building 1, Room 218, MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, smrb@mail.nih.gov, (301) 496-6837.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

The meeting will also be Webcast. The draft meeting agenda and other information about the SMRB, including information about access to the Webcast, will be available at http://smrb.od.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on

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campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April 21, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-9618 Filed 4-23-10; 8:45 am]
BILLING CODE 4140-01-P

May 17, 2010

Dr. Francis Collins
Director
National Institutes of Health
Building 1
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

We the undersigned organizations – representatives of diverse patient communities and in many cases funders of medical research – share the common goal of translating the promising discoveries coming from basic science into new treatments and cures for the patients we serve. For that reason, the following 87 organizations support new approaches that maximize the resources of our nation's medical research enterprise and support collaboration among all the stakeholders involved. The National Institutes of Health (NIH) is, of course, at the center of that enterprise, and a key component of NIH's investment is the research effort on its own campus, the Intramural Research Program (IRP).

We have been pleased to see the NIH's Scientific Management Review Board (SMRB) take up the issue of the organization and management of the IRP, and specifically the fiscal sustainability and utilization of the Clinical Center. We are writing to offer our support for one of the actions we understand is under consideration by the Board and the NIH, and that is opening up the Clinical Center facilities for greater use by the external research community.

As you are well aware, the Clinical Center is the largest dedicated research hospital in the country, and its existence in the IRP represents one of NIH's most unique resources. It provides some of the nation's best imaging equipment, phenotyping expertise, and access to a wide range of clinical research specialists. As a world-class facility, it has the potential to excel in research efforts focused on rare and orphan diseases and on pre-clinical and methods research essential to building tools, platforms, and protocols for the entire clinical research enterprise.

Yet the Clinical Center is an underutilized facility, and its potential as a national resource for the public health is not being fully realized. We believe that allowing and promoting greater use of the facility by external researchers is an important way for the Clinical Center to not only increase its utilization but to achieve its vision to "lead the global effort in training today's investigators and discovering tomorrow's cures."

We would like to see the NIH:

- Create streamlined mechanisms by which external researchers can more fully use the Clinical Center for projects in collaboration with the IRP. This might include giving the Clinical Center and/or Institutes the flexibility and authority to negotiate broader collaborative agreements or public-private partnerships, taking into consideration ethics rules and intellectual property rights;

- Explore the possibility of the Clinical Center controlling a pool of funds to make use of the facility feasible for investigators who otherwise could not afford it, for example through a program similar to the existing Bench-to-Bedside Awards.

We thank you for the opportunity to provide this input, and we look forward to working with you to ensure that the Clinical Center's resources are being put to their highest and best use.

Sincerely,

Accelerate Brain Cancer Cure
Accelerated Cure Project for Multiple Sclerosis
Aeras Global TB Vaccine
Alliance for Aging Research
Alpha-1 Foundation
Alzheimer's Foundation of America
Alzheimer's Association
American Autoimmune Related Diseases Association
American Institute for Medical and Biological Engineering
ARPKD/CHF Alliance
Autism Society
Beyond Batten Disease Foundation
Bonnie J. Addario Lung Cancer Foundation
Breast Cancer Network of Strength
Californians4Cures
Cancer Research Institute
Celiac Disease Center at Columbia University
CHDI Foundation, Inc.
Children's Neurobiological Solutions
Children's Rare Disease Network
Children's Tumor Foundation
Chordoma Foundation
Coalition for Pulmonary Fibrosis
Coalition of Heritable Disorders of Connective Tissue
Colon Cancer Alliance
COPD Foundation
Cure Alzheimer's Fund
Curing Kids' Cancer
Cutaneous Lymphoma Foundation
Cystic Fibrosis Foundation
Damon Runyon Cancer Research Foundation
Detroit Medical Reserve Corps
Dr. Susan Love Research Foundation
Epilepsy Therapy Project
FasterCures/The Center for Accelerating Medical Solutions
FOD Family Support Group
Foundation for Prader-Willi Research
Foundation for Sarcoidosis Research
Genetic Alliance

International AIDS Vaccine Initiative
Jacob's Cure
Jeffrey Modell Foundation
Joubert Syndrome and Related Disorders Foundation
Kidney Cancer Association
Klinefelter Syndrome and Associates
Life Raft Group
LIVESTRONG
Lung Cancer Alliance
Lung Cancer Circle of Hope
Medicines for Malaria Venture
Melanoma Research Alliance
Mesothelioma Applied Research Foundation
MHE Research Foundation
Michael J. Fox Foundation for Parkinson's Research
Multiple Myeloma Research Foundation
National Eczema Association
National Foundation for Ectodermal Dysplasias
National Health Council
National Indian Health Board
New York Stem Cell Foundation
Pachyonychia Congenita Project
Parkinson's Action Network
Partnership for Compassionate Use Therapies
Prader-Willi Syndrome Association (USA)
Progeria Research Foundation
Prostate Cancer Foundation
Pulmonary Fibrosis Foundation
PXE International
Rare Disease Foundation
Reflex Sympathetic Dystrophy Syndrome Association
Rett Syndrome Research Trust
Royal National Institute for Deaf People
Sarcoma Foundation of America
Seattle Biomedical Research Institute
Society for Women's Health Research
Solving Kids' Cancer
The AIDS Institute
The Alzheimer's Drug Discovery Foundation
The Leukemia & Lymphoma Society
The Nicholas Conor Institute for Pediatric Cancer Research
The RARE Project
The Sturge-Weber Foundation
Translational Genomics Research Institute
Tuberous Sclerosis Alliance
Van Andel Research Institute
VascularCures - The Foundation for Accelerated Vascular Research
VHL Family Alliance