

# I. INTRODUCTION

The National Institutes of Health (NIH) Reform Act of 2006 (Public Law 109-482) reaffirmed certain organizational authorities of agency 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 Reform Act also established the Scientific Management Review Board (hereinafter, SMRB or Board) to advise the NIH Director and other appropriate agency officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

This report distills the deliberations of the Substance Use, Abuse, and Addiction (SUAA) Working Group, a subcommittee of the SMRB, and provides recommendations in response to the question of whether organizational change within NIH could further optimize research into substance use, abuse, and addiction and thereby improve the health and well-being of individuals affected by this significant problem in public health.

## A. Impetus for and Charge to the SUAA Working Group

Over the past several decades, groups and individuals have questioned whether the current organization at NIH, with separate research institutes focused on drugs and alcohol use, abuse, and addiction, provides the optimal infrastructure for supporting these areas of scientific research.<sup>1</sup> In 2003, an expert panel convened by the National Academies advocated undertaking a study to evaluate a potential merger of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA). This panel also recommended that the proposed study be formally subjected to a process of public scrutiny and consideration.

In light of this question and prior recommendations, at the inaugural SMRB meeting on April 27-28, 2009, Board members unanimously agreed to convene the SUAA Working Group. The SUAA Working Group was asked to recommend to the full SMRB whether organizational change within NIH could further optimize research into substance use, abuse, and addiction and maximize human health and/or patient well-being.

## B. Working Group Process

In addressing its charge, the SUAA Working Group included the following in its considerations:

- Scientific opportunities, public health needs, and new research technologies;
- Research in these areas under the existing NIH structure;

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<sup>1</sup> Lewin and Associates. Examination of the Advisability and Feasibility of Restructuring Federal Alcoholism, Drug Abuse and Mental Health Activities. (1988). Washington, D.C.; NAS. Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges (2003). Washington, D.C.: National Academies Press.

- 41 • Criteria for contemplating changes in the organization and management of NIH;
- 42 • Strategies for implementing changes in the organization and management of NIH; and
- 43 • Metrics and methodologies that could be used for evaluating the impact of changes in the
- 44 organization and management of NIH.

45

46 The SUAA Working Group met twelve times by teleconference, three times in person, and  
47 hosted two public forums (September 23, 2009 and May 18, 2010) to solicit input from experts  
48 and stakeholders. Briefings were provided on the following topics (see Appendix A for a list of  
49 individual speakers and dates):

- 50 • Introduction to SUAA research at NIH from current NIAAA and NIDA directors;
- 51 • Public health needs in SUAA research, with perspectives from prevention specialists,  
52 treatment providers, patient advocates, and policy specialists;
- 53 • The science of SUAA research, with perspectives from distinguished scientists;
- 54 • Alternative models for organizing SUAA research, with perspectives from members of  
55 the judicial system, academia, and industry;
- 56 • The potential reorganization of SUAA research, with perspectives from former NIAAA  
57 and NIDA directors; and
- 58 • Options for organizational change, with perspectives from members of the community,  
59 treatment and prevention specialists, early stage investigators, and current NIH grant  
60 holders.

61

62 On February 3, 2010, the Chair of the SUAA Working Group briefed the advisory councils of  
63 NIAAA and NIDA on the reorganization options under consideration by the SUAA Working  
64 Group and received input from members of both advisory councils. On February 22, 2010, the  
65 Chair of the SUAA Working Group briefed the NIH Director, the Chair of the SMRB, and the  
66 Chair of the Intramural Research Program Working Group on the status of its deliberations. The  
67 SUAA Working Group also provided continual updates to and solicited input from the entire  
68 SMRB during its public deliberations held on November 13, 2009, March 10, 2010, and May 18-  
69 19, 2010.

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## 72 **II. HISTORY OF SUBSTANCE USE, ABUSE, AND ADDICTION**

### 73 **RESEARCH AT NIH: ORIGINS OF NIAAA AND NIDA**

74

#### 75 **A. Organizational History**

76

77 During the early 1970s, pressure to address the needs of persons suffering from substance use  
78 disorders resulted in the passage of several legislative provisions, which ultimately led to the  
79 establishment of the precursors to the current NIAAA and NIDA. The Comprehensive Alcohol  
80 Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 mandated the  
81 establishment of NIAAA as a separate entity within the National Institute of Mental Health  
82 (NIMH) at NIH. Concurrently, heightened concern regarding illicit drug abuse resulted in a rapid

83 expansion of drug abuse programs supported by NIMH. The Drug Abuse and Treatment Act of  
84 1972 subsequently mandated the establishment of NIDA, also to be housed within NIMH.

85  
86 In 1973, the Assistant Secretary for Health established a task force, in part, to determine how to  
87 administer the needs for research, services, and training in the alcoholism, drug abuse and mental  
88 illnesses fields. Through the course of their deliberations, the group concluded that the fields of  
89 drug abuse and alcohol abuse should be combined steadily because: 1) basic research and  
90 training needs were thought to be similar; and 2) because of the increasing number of people  
91 who abused both drugs and alcohol. The task force also noted differences between the substance  
92 abuse and “mental health fields,” despite their close historical association in research and  
93 practice.<sup>2</sup>

94  
95 In 1974, the Secretary of Department of Health, Education, and Welfare (now the Department of  
96 Health and Human Services) removed NIAAA, NIDA, and NIMH from the NIH and established  
97 them as autonomous institutes under the newly created Alcohol, Drug Abuse, and Mental Health  
98 Administration (ADAMHA). This reorganization elevated NIAAA and NIDA to equal status  
99 with NIMH, and each institute’s mission included research, training, and services. This  
100 reorganization became a matter of controversy in 1987, when some scientists and the National  
101 Alliance for the Mentally Ill (NAMI) expressed the view that research funding was lagging as a  
102 result of NIMH's placement within ADAMHA, which housed both services and research  
103 programs. These groups advocated for legislation mandating the return of NIMH to NIH. NAMI  
104 also favored the transfer of NIDA and NIAAA to NIH, although this was not included in the  
105 proposed legislation.

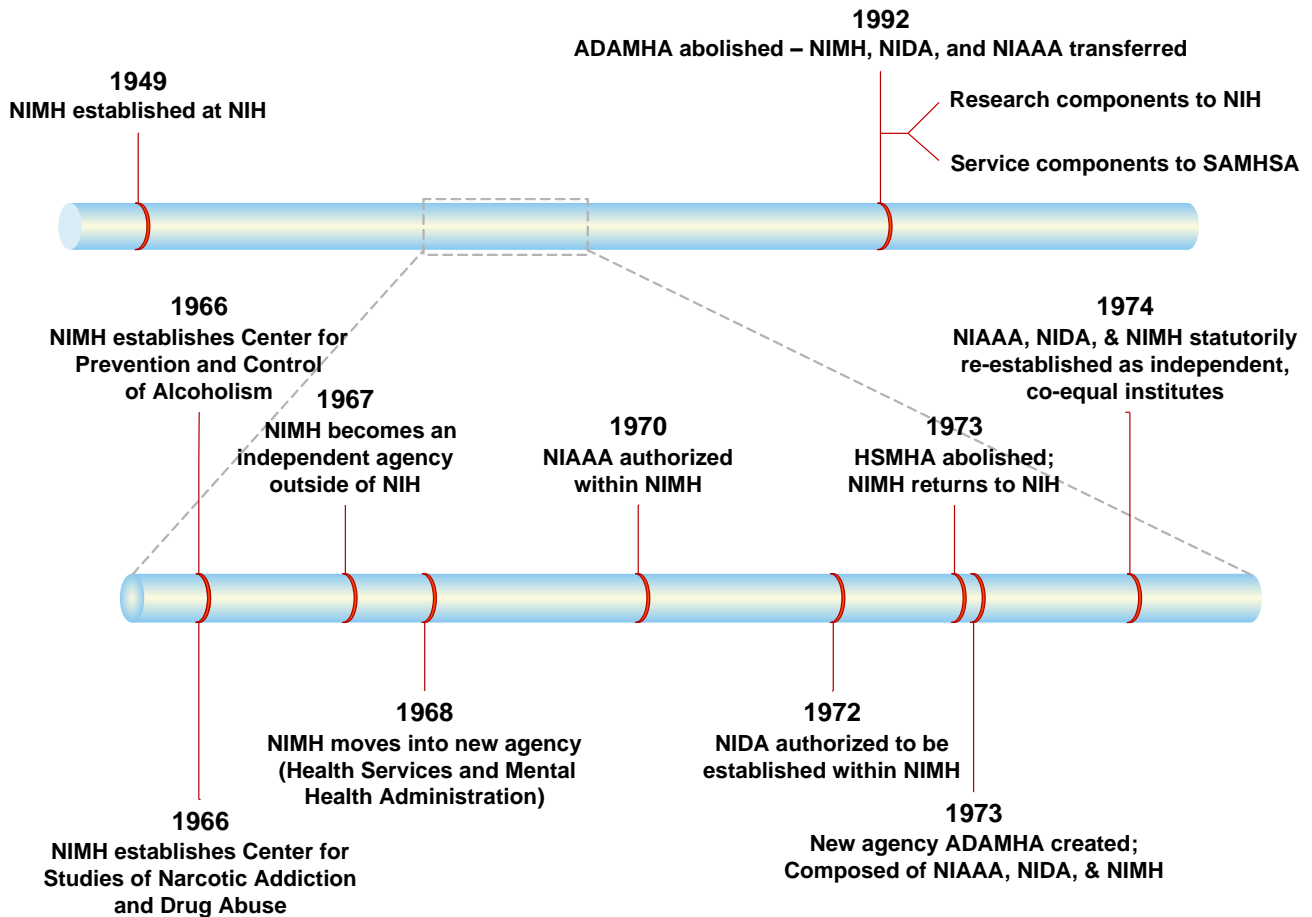
106 The debate over the optimal organization of basic research and health services programs  
107 continued over the next decade, with renewed concerns regarding the merits of having these  
108 components housed together.<sup>3</sup> In 1987, the Senate requested a position statement from the  
109 Department of Health and Human Services (DHHS), which in turn commissioned Lewin and  
110 Associates to investigate the organizational options for ADAMHA and the organizational  
111 preferences of interested parties. Ultimately, ADAMHA was dissolved in 1992 and the research  
112 components of NIMH, NIDA, and NIAAA were transferred back to NIH as independent  
113 research institutes. The services components of ADAMHA became the Substance Abuse and  
114 Mental Health Services Administration (SAMHSA).

115 **Figure 1. Organizational history for NIAAA and NIDA.**

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<sup>2</sup> E. A. Gardner, *Final Report of the Mental Health Task Force* (Washington D.C.: Department of Health and Human Services, 1973).

<sup>3</sup> Institute of Medicine. (1991). *Research and Service Programs in the PHS: Challenges in Organization*. Washington, D.C.: The National Academies Press.



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## 117 B. Previous Assessments and Recommendations

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119 As the organizational history of these institutes shows, the optimal organization of SUAA  
 120 research has been a topic of recurring debates for several decades. In 1988, Lewin and  
 121 Associates recommended considering the creation of a combined institute on addiction.<sup>4</sup> Several  
 122 years later, the Drug Abuse Education, Prevention, and Treatment Act of 2001 required the  
 123 Department of Health and Human Services (DHHS) Secretary to request an Institute of Medicine  
 124 study to determine whether combining NIDA and NIAAAA would strengthen scientific research  
 125 efforts and increase economic efficiency; however, this study has yet to be conducted.

126

127 In 2003, in response to a Congressional request to review the organizational structure of NIH, the  
 128 National Academies recommended that NIH undertake a study to determine whether NIAAAA  
 129 and NIDA should be merged.<sup>5</sup> The National Academies report asserted that the arguments for  
 130 combining the two institutes “stem from overlap in their missions and substantive foci.” The  
 131 report also noted public statements made by the directors of both institutes about the strong  
 132 association between the use of tobacco and illicit drugs and the abuse of alcohol. The report also  
 133 noted that:

<sup>4</sup> Lewin and Associates, op. cit.

<sup>5</sup> NAS, op. cit.



180 public health landscape with an eye towards scientific opportunities and unmet public health  
181 needs. The following themes emerged throughout the course of deliberations:

182

183 *i. Advances in Neuroscience*

184

185 Research in neuroscience has revealed that many substances with the potential for abuse may  
186 have similar effects on the brain. For example, while alcohol and cocaine activate different  
187 receptors and have unique physiological and behavioral effects, research suggests that the  
188 compulsion towards addiction often shares a common pathway.

189

190 According to testimony provided to the SUAA Working Group, unique genetic sites have been  
191 associated with risk for specific disorders related to alcohol and several drugs of abuse. With  
192 regard to the rewarding properties of addiction, although different drugs activate different  
193 receptors in the brain, they all either directly or indirectly elevate dopamine levels in the limbic  
194 system, which acts as the brain's endogenous reward system. Stimulation of this circuitry  
195 produces feelings of euphoria, motivates behaviors necessary for survival, and can result in a  
196 learned association between substance use and pleasure, which is believed to underpin repeated  
197 behaviors and addiction. Thus, understanding addiction as a usurpation of normal reward-related  
198 learning suggests that prevention and treatment strategies may be transferable across addictions.

199

200 Moreover, there is substantial evidence that addiction is a developmental disease; the roots of  
201 abuse and addiction across multiple substances take hold in adolescence and the teen years,  
202 suggesting commonalities in the initial developmental pathways and key windows of opportunity  
203 for prevention and intervention.

204

205 *ii. Co-Morbidity*

206

207 Many substance abusers suffer from multiple drug dependencies and/or co-morbid conditions.  
208 Some data suggest that treating one disorder without concurrently treating the other can lead to  
209 higher relapse rates for either substance. In addition, common pathways across multiple forms of  
210 compulsive behaviors offer unique opportunities for developing potential therapeutic strategies.  
211 For example, cannabinoids and alcohol activate similar reward pathways, and cannabinoid 1  
212 receptors may regulate the reinforcing effects of alcohol and mediate alcohol relapse.<sup>6</sup> There also  
213 are commonalities among psychological and behavioral interventions for substance abuse,  
214 including cognitive behavioral therapy, contingency contracting, and motivational enhancement  
215 therapy.

216

217 Imperative to this discussion is the complex relationship between substance abuse and mental  
218 health disorders. Data indicate that as of 2008, 2.5 million adults suffer from both a substance  
219 use disorder and a serious mental illness.<sup>7</sup> Data also indicate a link between major depression and  
220 substance abuse, and suggest that there is a unique relationship among the two across

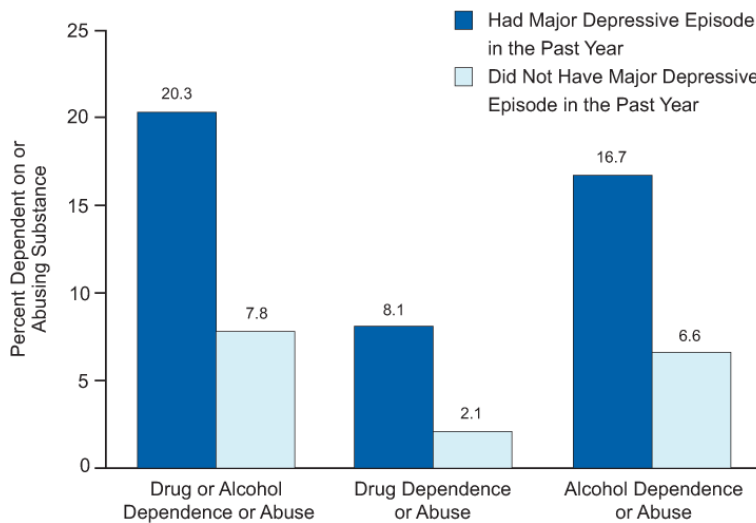
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<sup>6</sup> Herbert Kleber, October 23, 2009 presentation to the Working Group.

<sup>7</sup> Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

221 development. For example, 16 percent of adults reporting a major depressive episode in the past  
 222 year abused or were dependent upon alcohol, while only 8 percent abused or were dependent  
 223 upon drugs (not specified as licit or illicit; Figure 2). Regarding adolescent use, 37 percent of 12-  
 224 17 year olds suffering from a major depressive disorder in the last year reported using illicit  
 225 drugs<sup>8</sup>. The intersection of mental health status and substance use provides an additional  
 226 opportunity for advancing research with the end goal of improving public health.

227  
 228 **Figure 2. Substance dependence or abuse among adults aged 18 or older, by major**  
 229 **depressive episode in the past year: 2008.**



230  
 231 **SOURCE:** Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National*  
 232 *Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS  
 233 Publication No. SMA 09-4434). Rockville, MD.

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 235  
 236 **B. Unaddressed Scientific Opportunities and Public Health Needs**

237  
 238 The Working Group specifically requested from both NIAAA and NIDA a list of scientific  
 239 opportunities and public health needs in SUAA research that currently are addressed  
 240 insufficiently by either institute. Their responses are as follows:

241  
 242 NIAAA Perspectives:

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<sup>8</sup> Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

- 243 • A compendium of the pharmacokinetic and pharmacodynamic interactions between  
244 alcohol and the therapeutics used to treat general medical and psychiatric conditions (e.g.,  
245 hypertension, diabetes, epilepsy, depression, etc.);
- 246 • Research on the generation of novel metabolites resulting from the *in situ* interaction of  
247 alcohol with opiates, stimulants, hallucinogens, or inhalants (e.g. the production of coco-  
248 ethylene) and their pharmacokinetic and pharmacodynamic properties and toxicity;
- 249 • Mechanisms by which alcohol increases risk for certain cancers; and
- 250 • Encouragement of patients who are hesitant to seek treatment.

251  
252 **NIDA Perspectives:**

- 253 • Lack of pharmaceutical industry interest in developing medications to treat  
254 addiction/alcoholism;
- 255 • Insufficient involvement of the medical community in preventing and treating drug  
256 addiction and alcoholism;
- 257 • Relatively low rates of treatment by individuals with substance abuse, despite available  
258 treatments; and
- 259 • A bottleneck in translating treatments for substance abuse from bench to bedside to the  
260 community.

261  
262 Through careful analyses of the incidence and prevalence of various forms of substance use,  
263 abuse, and addiction,<sup>9</sup> the Working Group identified adolescent and young adult substance use as  
264 an area of research that warrants further attention. Of note, the Working Group learned that age  
265 of first use of alcohol was correlated with future abuse and/or dependence. A similar correlation  
266 exists for illicit drugs, as those who first used marijuana by the age of 14 were more likely abuse  
267 or be dependent upon illicit drugs than those who first tried marijuana at 19 (13.5% vs. 2.2% of  
268 adults). Moreover, in 2008, the highest prevalence of substance dependence or abuse occurred  
269 among young adults, ages 18-25(20.8%), followed by youth who are 12-17 years old (7.6%),  
270 followed by adults who are 26 and older (7.0%). These data suggest an urgent need to target  
271 effective prevention, intervention, and treatment strategies towards these populations.

272  
273 **C. Stakeholder Perspectives on Structural Reorganization of NIDA and NIAAA**

274  
275 Throughout its deliberations, the SUAA Working Group was met with diametrically opposed  
276 opinions regarding the potential reorganization of SUAA research at NIH. Even the respective  
277 scientific advisory councils of both NIAAA and NIDA were opposed in their recommendations  
278 to the Working Group. On February 4, 2010, the NIAAA Advisory Council passed a resolution  
279 (14 favored; 0 opposed; 1 abstained) strongly advising NIH against a reorganization that  
280 eliminates NIAAA as an independent institute. The resolution encouraged “increased

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<sup>9</sup> Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Se3es H-36, HHS Publication No. SMA 09-4434). Rockville, MD.



281 collaboration across NIH institutes and centers to strengthen research on the use, abuse, and  
282 addiction to alcohol, tobacco, drugs of abuse, and high-fat and high-sugar foods. We also  
283 advocate increased collaboration to improve the diagnosis and treatment of the co-morbid mental  
284 health disorders associated with addiction” (see Appendix B for full resolution). On March 1,  
285 2010, the NIDA Advisory Council unanimously passed a resolution (15 favored; 0 opposed)  
286 supporting the creation a single entity for all drug use and addiction and recommended that the  
287 Secretary of DHHS and the NIDA Director “vigorously should support efforts to combine and  
288 focus within a single NIH institute research on the causes, mechanisms, prevention, and  
289 treatment of the non-medical use of, and addiction to, all addictive drugs,” (see Appendix C for  
290 full resolution).

291  
292 These resolutions generally reflect the views of respective NIAAA and NIDA staff, grantees, and  
293 constituency groups. In summary, both the alcohol and drug research communities largely favor  
294 increased collaboration between the two institutes. However, the drug research community  
295 believes that increased collaboration would be achieved best through a structural merger of the  
296 two institutes. The alcohol research community believes that these objectives could be achieved  
297 without a structural merger and caution that this type of reorganization might jeopardize  
298 advances in alcohol research. A summary of each perspective is provided in the following  
299 subsections. In part, because of the context within which these deliberations are occurring, a  
300 great deal of discussions focused on the disposition of NIDA and NIAAA. Therefore, many of  
301 the perspectives address a merger of NIDA and NIAAA or a non-structural approach to  
302 increasing collaborations between these two institutes.

303  
304 ***i. Arguments in Favor of a Structural Reorganization***

305  
306 *Scientific Synergies.* As noted above, emerging scientific research indicates that similar reward  
307 pathways underlie compulsive behavior and addiction. In addition, similar risk factors are  
308 associated with use and abuse of drugs and alcohol, and similar behavioral therapies and  
309 prevention strategies can be employed regardless of substance. Some stakeholders argue that a  
310 structural reorganization is the most effective way to capitalize on these synergies.

311  
312 Furthermore, given these scientific similarities, as previously noted, external analysts such as  
313 Lewin and Associates and the National Academies have questioned whether the current  
314 organization at NIH, with separate research institutes on drug abuse (NIDA) and alcohol use,  
315 abuse, and addiction (NIAAA) provides the optimal infrastructure for supporting these areas of  
316 scientific research.

317  
318 *Underserved Patient Populations.* Proponents of a structural reorganization have argued that  
319 segregating these disciplines creates gaps in addressing public health. Given that a high  
320 prevalence of individuals use both drugs and alcohol, proponents of a structural reorganization  
321 view the current organization with NIAAA and NIDA as insufficient to meet the needs of this  
322 population. For example, one NIDA Advisory Council member asked, “My patients have no  
323 problem mixing drugs and alcohol – why do you?”

324  
325 Moreover, given the early risk factors for use, often burgeoning during adolescence—this  
326 population represents a key window of opportunity for prevention and intervention. Proponents

327 of a structural reorganization stress that the current organizational structure does not sufficiently  
328 meet the needs of this population.

329  
330 *Impediments to Collaboration and Integration.* Proponents of a structural reorganization cite  
331 cultural barriers as significant obstacles hindering effective communication and collaboration  
332 between the alcohol and drug abuse research communities. They argue that these hurdles can be  
333 overcome only through a structural merger of NIAAA and NIDA. For example, there are distinct  
334 professional societies for the two research communities and insufficient communication between  
335 them, despite areas of commonality.

336  
337 Similarly, some cited that these cultural barriers create significant challenges to training early  
338 stage investigators who are well equipped to participate in inter-disciplinary research teams.  
339 Structural reorganization was cited as an effective mechanism to enhance training and also  
340 incentivize early-stage investigators to pursue the field of addiction research.

341  
342 Given the large number of institutes and centers supporting relevant addiction research  
343 portfolios, some have argued that coordinating such a large initiative would be overly  
344 burdensome and ultimately, render the strategy ineffective. Moreover, these proponents argue  
345 that, to more effectively streamline collaboration and maximize integration, the agency should  
346 establish a clear structural home for this research.

347  
348 ***ii. Arguments in Favor of a Non-Structural Approach for Increasing Collaboration***

349  
350 *Potential Loss of Research.* Several researchers and constituency advocates, primarily from the  
351 alcohol research and treatment community, expressed concern that merging NIAAA and NIDA  
352 could diminish focus on (and funds for) alcohol research, resulting in the stagnation of discovery  
353 and oversight of critical end-stage organ pathology research. In part, this concern has been  
354 attributed to the differences in the budget of the two institutes: in Fiscal Year 2009, the NIAAA  
355 budget was \$450,095,000 and the NIDA budget was \$1,032,457,000. Subsequently in FY 2009,  
356 NIDA received 1,871 applications and funded 403 (21.5% success rate), while NIAAA received  
357 811 applications and funded 191 (23.6% success rate). This discrepancy in budget and,  
358 ultimately, portfolio size, perpetuates the fear of some that the larger institute will consume  
359 NIAAA in a structural merger of the two Institutes.

360  
361 In that same vein, numerous experts and stakeholders expressed concern that merging NIAAA  
362 and NIDA into a single addiction-focused institute could potentially eradicate the portions of  
363 each portfolio not focused on addiction. For example, NIAAA funds research on the end-organ  
364 effects of alcohol, in particular, the liver. Stakeholders who hold this concern underscored the  
365 potential loss that this research might sustain through a merger and argued that this issue should  
366 be a critical factor in the ultimate decision.

367  
368 *Establishment of a Research Dogma.* Some individuals expressed concern that centralizing  
369 addiction research within a single institute could result in a research dogma, potentially resulting  
370 in a loss of exploration of other mechanisms underlying this disease. They argued that it is  
371 inappropriate to constrict the focus of an issue as complex as addiction, and potentially valuable  
372 insights might be lost when this research is constrained to a single vision – and source of funding

373 – rather than two. Moreover, there are benefits to having multiple perspectives brought to bear  
374 on common questions. Functional integration around substance use, abuse, and addiction through  
375 increase coordination and collaboration has the added benefit of readily achieving the goal of  
376 enhanced collaboration for all of addiction research across NIH. For example, rather than  
377 focusing on structural reorganization of NIDA and NIAAA, a functional reorganization strategy  
378 could include components from NIMH, the National Institute of Neurological Disorders and  
379 Stroke (NINDS), the National Cancer Institute (NCI) and other institutes with relevant portfolios.  
380 This added benefit may be more difficult to achieve through a structural reorganization involving  
381 NIDA and NIAAA.

382  
383 *Examples of Current, Successful Collaborations.* Examples of existing collaborations between  
384 the two institutes were also cited, as some argued that effective collaborative efforts were already  
385 facilitated and supported in this area. In Fiscal Year 2008, 13 grants were co-funded by NIAAA  
386 and NIDA. In addition, among the common principal investigators, 112 received awards from  
387 both institutes. NIDA and NIAAA co-fund COGA (collaborative studies on the genetics of  
388 alcoholism) and NESARC (National Epidemiological Survey on Alcohol and Related  
389 Conditions), and NIAAA uses NIDA’s Clinical Trials Network at times.

390  
391 *Licit versus Illicit Substances.* Several stakeholders noted that NIAAA funds research concerning  
392 a legal substance, alcohol, and NIDA funds research concerning illicit drugs. Therefore, they  
393 argue that the two institutes should remain separate in order to maintain a consistent public  
394 health message with their respective target audiences. This argument is complicated by the fact  
395 that alcohol is also an illegal substance for individuals under the age of 21. Furthermore, concern  
396 was expressed regarding the stigma that would be attached to alcohol use if it were combined  
397 with illicit substances.

398  
399

#### 400 **IV. DELIBERATING ORGANIZATIONAL CHANGE FOR SUAA** 401 **RESEARCH AT NIH**

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403 The discussion of whether to undertake major organizational change was informed by a  
404 report developed by the SMRB entitled *Deliberating Organizational Change and*  
405 *Effectiveness*. This framework is to be used by the Board when considering  
406 organizational change at the NIH and its fundamental premise is that any rationale for  
407 organizational change at NIH must be to improve NIH’s ability to fulfill its mission. The  
408 three steps developed by the SMRB for the contemplation of organizational change at  
409 NIH include (1) assessing the need for change, (2) evaluating the options for change, and  
410 (3) navigating the change. This section outlines the Working Group’s findings on steps 1  
411 and 2, including the assessment of the need for change in the organization of SUAA  
412 research at NIH and the evaluation of the options for organizational change. (In light of  
413 the prospective nature of this work and of the group’s recommendations, it would be  
414 premature to speculate how the agency should navigate organizational change.)

415

##### 416 **A. Assessing the Need for Change**

417

418 Regarding the assessment of the need for change, the SUAA Working Group capitalized upon  
419 the existing body of research reported by the SMRB. In its report, the SMRB identified five  
420 categories of issues that may prompt the Board to consider recommending organizational  
421 change: an immediate crisis, unaddressed scientific opportunities, changes in the scientific  
422 landscape, evolving emergent public health needs, and the need for improvements in quality  
423 and/or efficiency of research. The first criterion, likely the most straightforward to assess, is  
424 whether an immediate crisis threatens the ability of NIH to fulfill its mission. In response to this  
425 question, the SUAA Working Group unanimously agreed that there are no existing  
426 organizational impediments significantly hindering NIH's conduct of SUAA research.

427  
428 Regarding the remaining four categories, albeit a bit more complex to assess, the Working Group  
429 identified several areas of scientific inquiry not sufficiently addressed due to the limitations  
430 imposed by the current organization. Opportunities for enhancement or a more targeted approach  
431 included preventing adolescent use, abuse, and addiction; promoting an understanding of both  
432 alcohol and drug abuse as diseases; and understanding drug-drug interactions. Members also  
433 agreed that changes in the scientific landscape have enabled new opportunities for innovation  
434 and advancement that could potentially benefit from reorganizing SUAA research within NIH. In  
435 addition, advancements in a systems-level understanding of addiction warrant a joint approach  
436 for many aspects of SUAA research.

437  
438 Looking forward, the group also identified evolving public health needs on the horizon that may  
439 create new challenges and opportunities that may be best faced by reorganizing existing  
440 components within NIH. These factors include populations suffering from co-morbid conditions  
441 associated with substance use, abuse, and addiction, and the rise in other forms of addiction (e.g.  
442 gambling, food, sex). Also relevant to this discussion is the training of future generations of  
443 SUAA researchers and the effective dissemination of information. The Working Group agreed  
444 that two areas that could benefit from enhanced coordination are the development of an  
445 integrated discipline of addiction research and strengthening cross training across fields.

446  
447 *After thorough analyses of the data and extensive discussion, the SUAA Working Group*  
448 *unanimously agreed that the status quo is not ideal for fulfilling the NIH mission and optimizing*  
449 *SUAA research.*

## 450 451 **B. Evaluating the Options for Organization Change in SUAA Research at NIH**

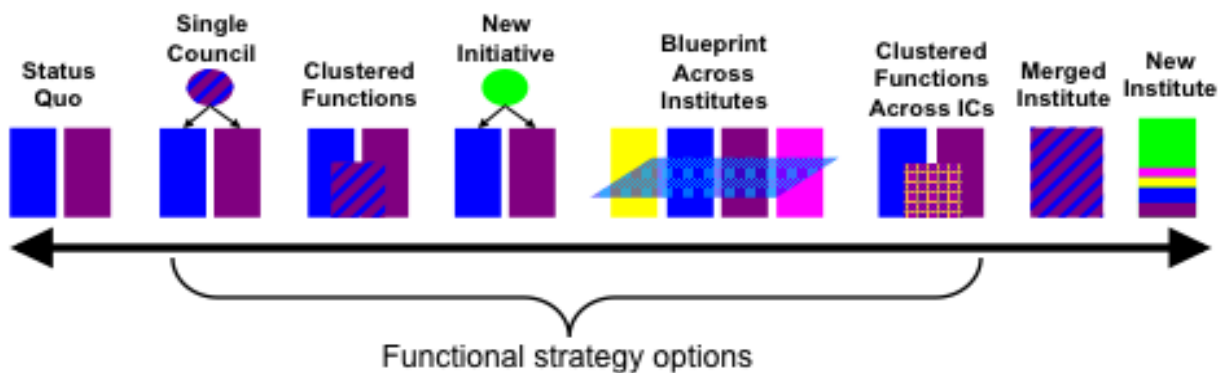
452  
453 The Working Group's assessment of the need for organizational change culminated in the  
454 conclusion that the status quo is not ideal for fulfilling the NIH's mission and advancing research  
455 into substance use, abuse, and addiction, and that organizational change is needed. Although  
456 initial discussions focused on two options – either leaving the institutes separate or merging them  
457 into one institute – the Working Group decided that it would be in the best interest of SUAA  
458 research to take a more holistic approach in examining potential options for reorganization.

459  
460 The options considered by the Working Group can be conceptualized along a spectrum of  
461 change, ranging from a variety of functional strategies through structural reorganization (see  
462 Figure 3). As defined by the SMRB, *functional* organizational change entails the design and  
463 implementation of new or different mechanisms for coordinating the work of existing

464 components, usually with the aim of realizing some as of yet unrealized goal. Such mechanisms  
 465 may take the form of committees, task forces, or consortia that bring together structural  
 466 components around shared foci, activities, and goals. As such, they are flexible and have the  
 467 potential to create and sustain new synergies. At NIH, there are nearly forty working examples of  
 468 functional strategies for organizational change. *Structural* organizational change entails the  
 469 creation of new organizational components and/or the merger or elimination of existing  
 470 components. The basic components of the NIH are its twenty-seven institutes and centers. Issues  
 471 under study include whether science and the public would be served best by merging NIAAA  
 472 and NIDA or whether there are other functional approaches to organizational change that would  
 473 catalyze greater synergy among the broad range of addiction sciences.  
 474

475 As depicted in Figure 3, a potential spectrum of options for reorganizing NIAAA and NIDA can  
 476 range from maintaining the status quo (left) to merging the two into a single institute. Also along  
 477 this spectrum include creating a new addiction research institute with addiction elements of  
 478 multiple institutes (right). In the middle are options for functional reorganization that require  
 479 increased collaboration between independent institutes. Functional strategy options include a  
 480 single advisory council for the two institutes or some shared functions, joint ventures, or a  
 481 blueprint for research in some areas across the institutes.  
 482  
 483

484 **Figure 3. Example of spectrum of options considered by the Working Group.**  
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486  
 487  
 488 In evaluating the options for organizational change, the Working Group focused on and, with  
 489 respect to the leading options, attempted to answer several questions, including:

- 490
- 491 • How can NIH increase synergy among researchers studying different facets of substance use, abuse, and addiction?
  - 492 • How can NIH best promote the development of treatments for multiple addictions/co-morbidities?
  - 493
  - 494 • How can NIH ensure that all areas of addiction, including addictive behaviors such as smoking and gambling, receive appropriate scientific attention?
  - 495

- 496 • How can organizational structure advance research on fundamental pathways underlying  
497 substance use and abuse, help develop new treatments for addiction, and help develop  
498 therapeutic applications of these substances?
- 499 • What are the strengths and weaknesses of various organizational options?
- 500 • Are other areas of research being examined for potential inclusion in a merged institute?
- 501 • Should the SMRB consider broadening the mission/scope of a merged institute focusing  
502 on drugs and alcohol to include addiction research more broadly?
- 503
- 504

## 505 V. SUAA WORKING GROUP RECOMMENDATIONS

### 506 A. Reject the status quo

507 As previously stated, the members of the SUAA Working Group unanimously agreed that the  
508 status quo is not ideal for fulfilling the NIH mission and optimizing substance use, abuse, and  
509 addiction research at the NIH. Research has changed our understanding of substances of abuse,  
510 revealing that the while differences exist between and among alcohol, illicit drugs, and tobacco,  
511 all are likely undergirded by similar or common neurobiological pathways of response and  
512 reward. The structure of NIH should evolve accordingly, not simply as a response to new  
513 discoveries, but also to lead ongoing efforts to advance our understanding of the fundamental  
514 bases of one of our nation’s most pressing public health problems. Specifically, the agency  
515 should act to bridge or dismantle barriers to collaboration in addiction-related research. To be  
516 sure, NIDA and NIAAA do currently collaborate on some addiction programs, but research and  
517 public health needs will be better served if addiction-related programs across NIH work together  
518 more closely. The ideal solution will reduce siloing and capitalize on evolving synergies between  
519 and among addiction research programs.

### 522 B. Key Features of Reorganization

523 *i. Integration of Addiction Research Portfolios across NIH.* Based upon close examination of  
524 the scientific opportunities and unmet public health needs cited by many of the experts  
525 consulted, the Working Group concluded that the scope of the proposed reorganization should be  
526 focused on addiction-related research, broadly defined to include more than just opportunities in  
527 drug and alcohol research. The goal of reorganization should be to capitalize upon existing  
528 synergies while facilitating the identification of new areas of opportunity in addiction research.

529 In light of the diverse interests across NIH, including substances (e.g., tobacco) and behaviors  
530 (e.g., gambling) with the potential for addiction, an emphasis on addiction research will  
531 necessitate inclusion of perspectives and portfolios from many institutes and centers. For  
532 example, research into the neurological pathways of addiction conducted by NIMH and NINDS  
533 would be crucial to advancing our understanding of addiction and could be strengthened through  
534 enhanced collaborations. Likewise, NCI’s addiction portfolio on tobacco-related research could  
535 make substantial contributions to these collaborative efforts, especially those targeted towards  
536 prevention and behavioral interventions. A reorganization effort confined to NIAAA and NIDA,  
537

540 while excluding these other addiction-related components of NIH research, would neither fully  
541 advance the science nor fully address the current opportunities and needs.

542  
543 The mission of the reorganized entity should reflect the diverse array of substances (e.g., alcohol,  
544 cocaine, tobacco, food) and behaviors (e.g., gambling, exercise, sex) that have demonstrated the  
545 potential for compulsive use and abuse, along with the range of behavioral stages that can lead to  
546 the prevention or facilitation of compulsive use (e.g., abstinence, abuse, addiction, etc.). The  
547 mission statement should be defined clearly and should promote:

- 548 • A new and unified vision for effectively meeting currently unmet scientific opportunities  
549 and unmet public health needs in research on substances and behaviors with the potential  
550 for abuse and addiction,
- 551 • An interdisciplinary approach to advancing the research missions of both NIAAA and  
552 NIDA, in addition to other relevant NIH institutes and centers,
- 553 • Flexibility for new areas of study as new and unexpected scientific opportunities and  
554 public health needs emerge, and
- 555 • A multidisciplinary approach to training new investigators.

556  
557 **ii. Commitment by all Participants to the Success of the Reorganization.** The success of any  
558 reorganization will depend decisively on the support and commitment of all participants—  
559 including the NIH Director, directors of relevant institutes and centers, participating and  
560 contributing NIH staff, and the community of affected researchers and stakeholders.  
561 Furthermore, strong leadership is critical to identifying and establishing priorities and making  
562 decisions. Leaders also must be held accountable for the success of the effort.

563  
564 A successful reorganization also will require a well defined and supported structure, sufficiently  
565 articulated and organized to identify the collaborative goals inherent in addressing unmet  
566 scientific and public health needs. A loosely defined committee meeting on an infrequent basis is  
567 unlikely to achieve the goals outlined in this report. A stable, dedicated budget, staff and  
568 resources also are essential to the success of any reorganization strategy.

569  
570 **iii. Functional Integration.** In part for ease of presentation, discussions to this point have  
571 focused on a distinction between functional and structural options for reorganization. It is  
572 important to acknowledge that a successful structural reorganization strategy must be  
573 underpinned by effective functional integration within the new structure. A structural  
574 reorganization is not merely a combination of existing parts under a new heading. The successful  
575 structure will need to be characterized by shared goals; enhanced communication and  
576 collaboration; engagement and participation from all relevant parties; identification, creation, and  
577 sustention of new synergies; and cultural shifts needed to realize these elements. This type of  
578 functional integration among existing and new components will be necessary for the success of  
579 either type of reorganization strategy.

## 580 581 **C. Two Options for Reorganization**

582

583 SUAA Working Group members developed two options for reorganizing SUAA research at the  
584 agency to maximize collaboration and facilitate progress in addiction research: (1) a single  
585 institute focused on addiction, in which all NIH addiction-related research would be relocated, or  
586 (2) a trans-NIH addiction program (like the Neuroscience Blueprint) with participation from all  
587 institutes and centers that fund addiction-related research. Although each option entails a certain  
588 degree of risk, each would yield a marked improvement over the status quo and could be  
589 successful with adequate support and leadership.

590  
591 The two optimal options are characterized in this section. The following section provides a  
592 synthesis of the arguments in favor of one option over the other.

593  
594 *i. Reorganization Option 1: Create a New Addiction Institute*

595  
596 The first option for advancing addiction research at NIH is to create a new institute devoted to  
597 addiction research. This new institute would integrate all relevant addiction research portfolios  
598 from NIAAA, NIDA, and other institutes at NIH. Non-addiction research portfolios currently  
599 held by NIAAA and NIDA would be transferred to other institutes as deemed appropriate, and  
600 the current NIAAA and NIDA would be dissolved. Funding for existing research should not be  
601 supplanted or reduced, but rather, relocated so that addiction-related programs are funded out of  
602 the addiction institute to achieve better integration and synergy across substance- and behavior-  
603 addiction research fields.

604  
605 *Research Portfolios.* NIH should conduct an agency-wide portfolio analysis of intramural and  
606 extramural research to determine which addiction-related programs should be included in the  
607 new institute. This analysis should include addiction research and its relevant precursors  
608 regarding use and abuse. Examples include, but are not limited to, drug addiction research from  
609 NIDA, alcohol addiction research from NIAAA, tobacco addiction research from NCI and other  
610 relevant institutes and centers, and gambling addiction research from NIDA and NIMH—  
611 including relevant basic, prevention, treatment, behavior, and policy research. In addition,  
612 portfolio analysis of NIDA and NIAAA should identify non-addiction research, and these  
613 programs should be reassigned to alternative institutes or centers. For example, research on  
614 alcohol liver disease could be reassigned to the National Institute of Diabetes and Digestive and  
615 Kidney Diseases (NIDDK) or research on Fetal Alcohol Spectrum Disorders could be reassigned  
616 to the National Institute of Child Health and Human Development (NICHD).

617  
618 *Funding.* In order to establish and fund a new addiction institute, Congress would need to  
619 authorize and appropriate its funding. Funding for all addiction-related research programs  
620 relocated from NIAAA, NIDA and other institutes should be redirected to the new institute.  
621 Funding for non-addiction and end-organ research programs relocated from NIAAA and NIDA  
622 to other institutes and centers should be reassigned to their new institute. Total funding for  
623 research in a particular field should not be reduced.

624  
625 *Organizational structure.* The new institute should consolidate structural components that are  
626 redundant across institutes and create new structural components necessary to support the newly  
627 defined mission.

628



629 *Leadership.* The NIH Director should form a search committee to identify, recruit, and hire a  
630 director for the new addiction institute. The new director should have a strong foundation in  
631 addiction research balanced across multiple substances of abuse and compulsive behaviors. The  
632 new director should also have a clear understanding of the scientific opportunities and public  
633 health needs in addiction research. The SUAA Working Group members recommend that the  
634 new director possess the confidence of NIAAA and NIDA staff, intra- and extramural  
635 researchers, and stakeholders.

636  
637 *Personnel.* The new institute should be staffed by current NIAAA and NIDA personnel and by  
638 individuals from other institutes and centers (as necessary) to achieve the new mission or to  
639 address gaps in research.

640  
641 *Strategic plan.* In combination, the new institute director and institute program staff should  
642 develop a strategic plan to advance addiction-related research. The strategic plan should be  
643 informed by the new mission statement, results of the NIH-wide portfolio analysis, NIAAA and  
644 NIDA Advisory Councils, NIAAA and NIDA intra- and extramural researchers, stakeholders,  
645 and the issues raised in this report.

646  
647 *Transition plan.* Given the lengthy process that must be undertaken to appoint a new director, a  
648 transition committee should be established to make the innumerable decisions necessary to  
649 implement this reorganization option. This committee should develop a transition plan that  
650 outlines the process for writing the name and mission statement, determining which research  
651 portfolios should be included, developing the organizational structure, and establishing a  
652 timeline to ensure progress is made in a timely manner.

#### 653 654 ***ii. Reorganization Option 2: Form a Trans-NIH Initiative on Addiction***

655  
656 The second reorganization option for advancing addiction research at NIH is to establish a trans-  
657 NIH collaborative initiative, similar to the NIH Blueprint for Neuroscience Research or the  
658 newly created Basic Behavioral and Social Science Opportunity Network (OppNet). All existing  
659 institutes would remain intact, but those with relevant addiction-related research portfolios would  
660 be integrated within the new program.

661  
662 *Research portfolio.* Institutes with addiction-related research portfolios would participate in the  
663 new initiative and contribute to the integration of addiction research. NIH should conduct a  
664 portfolio analysis of extramural and intramural research to survey the current landscape of  
665 addiction research supported by NIH, in addition to identifying all relevant programs and  
666 research gaps.

667  
668 *Funding.* Stable, dedicated funding is essential to the success of a multi-institute collaborative  
669 approach such as the one envisioned for addiction-related research. For the proposed strategy to  
670 be successful, each institute must include a substantial amount of their addiction portfolio funds;  
671 otherwise, the initiative will have only marginal effects. It is the opinion of several Working  
672 Group members that the majority of each institute or center's addiction funds should be devoted  
673 to this effort. The SUAA Working Group recommends that the NIH Office of the Director also

674 contribute to the initiative to supplement individual institute and center contributions and to  
675 demonstrate the NIH Director’s commitment to its success.

676  
677 *Organizational structure and leadership.* A steering committee should be established to lead the  
678 new initiative. Members should include institute and center directors whose respective institutes  
679 have research portfolios that fall under the mission of the initiative. The steering committee  
680 should be co-chaired by four or five institute or center directors: NIAAA and NIDA should each  
681 have a permanent seat, while the remaining two or three seats should be rotated among the other  
682 steering committee members. Working groups or coordinating committees should be established  
683 to carry out the main work of the initiative-addressing, for example, specific areas of addiction  
684 research, strategic planning activities, and the development of an evaluation plan for the  
685 initiative. Subject matter experts from the participating institutes and centers should constitute  
686 these committees. Mechanisms should be put in place to ensure that the steering committee is  
687 held accountable for the success of the initiative.

688  
689 *Personnel.* The new initiative should be staffed by NIAAA and NIDA personnel and by  
690 individuals from the other institutes and centers (as necessary) to achieve the new mission or to  
691 address gaps in research. The initiative should have dedicated staff for its day-to-day operations.

692  
693 *Strategic plan.* The steering committee should develop a strategic plan to advance addiction-  
694 related research. The strategic plan should be informed by the new mission statement, results of  
695 the NIH-wide portfolio analysis, and the issues raised in this report. Public and stakeholder input  
696 will also be essential in developing the strategic plan.

697  
698 *Evaluation.* Clear metrics should be established to determine whether the initiative is successful  
699 in achieving its mission. For example, clear and tangible outputs should be identified to measure  
700 collaborations, programs, activities, training opportunities, etc. The steering committee should  
701 use these results to refine its approach, as necessary. It is critical that the steering committee have  
702 the authority and willingness to terminate efforts that are not successful. If a particular activity or  
703 program is not meeting intended goals, those resources and attention should be devoted to  
704 activities that offer more promise.

#### 705 706 **D. Summary of Arguments in Support of Reorganization Options 1 and 2**

707  
708 Throughout their deliberations, members of the SUAA Working Group remained committed to  
709 their assessment that the status quo is no longer acceptable and that the science underlying  
710 SUAA research would benefit from reorganization to capitalize upon existing synergies and  
711 address unmet opportunities and needs. Despite this consensus, the group remained divided  
712 regarding the form that reorganization should take, with some members favoring the creation of  
713 a new institute focused on addiction (Option 1) and others favoring the formation of a trans-NIH  
714 initiative focused on addiction (Option 2).

715  
716 The perspectives of the stakeholder communities (reflected in section III.C. above) resonated  
717 with the Working Group. In addition to those perspectives, the following arguments in favor of  
718 either Option 1 or Option 2 arose in the context of Working Group discussions.

719

720 ***i. Arguments in Favor of Creating a New Institute Focused on Addiction (Option 1)***

721  
722 Members of the Working Group found the unaddressed scientific opportunities and unmet public  
723 health needs particularly compelling. Proponents of Option 1 strongly believe that the formation  
724 of a trans-NIH initiative would be insufficient and unsuccessful in advancing science around  
725 these unaddressed opportunities and unmet needs. They noted the stark divergence between two  
726 of the primary scientific communities concerns, which is mirrored in the separation of their  
727 respective scientific associations (The Research Society on Alcoholism and the College of  
728 Problems on Drug Dependence). Those in favor of Option 1 argued that this separation can only  
729 be remedied by merging the two fields and establishing a new institute.

730  
731 Additional arguments include that the existence of separate institutes for alcohol and drugs  
732 perpetuates the misconception, especially among youth, that alcohol is not, in fact, a drug.  
733 Proponents of creating a new institute argue that in order to develop a clear and cohesive public  
734 health message that alcohol has similar detrimental effects on the brain and body as other illicit  
735 drugs, these two institutes should be combined.

736  
737 Option 1 also would provide a highly visible home for addiction research at NIH. By creating a  
738 single institute, comprehensive training programs integrating both multi- and interdisciplinary  
739 approaches to addiction research could be developed and supported. Moreover, a visible “home”  
740 for this type of research could indicate stability and enhance the recruitment of new investigators  
741 to the field. Research on the effects of alcohol on multiple organ systems would be preserved  
742 and, potentially, enhanced by relocating this portfolio to institutes and centers possessing  
743 expertise in these relevant areas.

744  
745 Finally, the Working Group members advocating for Option 1 are convinced that the effective  
746 promotion of research on polysubstance substance use, abuse and addiction and a greater  
747 understanding of adolescent users is dependent on a unified structural framework in which  
748 substance- and behavior-based addiction research fields are thoroughly integrated.

749  
750 All members acknowledged that success of a new institute would depend on leadership from the  
751 NIH Director and the Director of the new addiction institute. Success will also depend on  
752 participation, cooperation and support from institute staff, intra- and extramural researchers, and  
753 stakeholders.

754  
755 ***ii. Arguments in Favor of Forming a Trans-NIH Initiative Focused on Addiction (Option 2)***

756  
757 Working Group members in favor of Option 2 agreed with the concerns identified by those in  
758 favor of a Option 1, but remained unconvinced that the creation of a new institute would produce  
759 significant change that could not be achieved through a trans-NIH initiative. In their view, a  
760 collaborative strategy deployed across the agency could just as well address the scientific  
761 opportunities and public health needs, while minimizing the disruption and potential unintended  
762 consequences of a comprehensive structural reorganization. They pointed to evidence that other  
763 trans-NIH initiatives have worked in the past in other scientific areas, albeit with varying degrees  
764 of success (e.g., Neurosciences Blueprint, NIH Common Fund).

765

766 Advocates of a forming a trans-NIH initiative expressed concern that creating a new institute  
767 might create research gaps in understanding alcohol’s ubiquitous effects on the body and the  
768 unique factors contributing to its abuse. Option 2, however, would preserve the unique research  
769 conducted within each institute—for example, NIAAA’s portfolio on the effects of alcohol on  
770 multiple organ targets—while capitalizing upon synergies across the entirety of NIH. This  
771 approach also yields the added benefit of flexibility to reconfigure component programs and  
772 initiatives as needed in response to emerging scientific opportunities and public health needs.  
773

774 An additional argument in favor of Option 2 is the recognition that the establishment of a new  
775 institute would constitute a significant undertaking, demanding considerable time and effort from  
776 the NIH Director and NIH staff. The dissolution of NIAAA and NIDA and creation of the new  
777 institute described in Option 1 would cause considerable disruptions in the research community  
778 as well; although some of these disruptions would be short-term, there would likely be long-term  
779 implications of this change. Many Working Group members questioned whether the potential  
780 value gained from Option 1 was sufficient to warrant the pains that would necessarily  
781 accompany the creation of a new institute.  
782

783 Although both Options 1 and 2 call for the inclusion of relevant programs across NIH, forming a  
784 trans-NIH initiative has the added benefit of an inherently interdisciplinary component. The  
785 creation of a new institute would include a variety of perspectives initially, with components and  
786 portfolios from various institutes and centers, but would likely, in the judgment of these Working  
787 Group members, tend to engender a single discipline or culture within the agency. A trans-NIH  
788 initiative would continuously draw on a variety of perspectives with representatives coming from  
789 institutes and centers across NIH and continuing to bring those unique perspectives to the table.  
790

## 791 792 **VI. SUAA WORKING CONCLUSIONS**

793  
794 In conclusion, although these points have been stressed repeatedly, each warrants a final  
795 iteration. First, the working group is committed to the finding that the current organization of  
796 SUAA research at NIH is not optimal for fulfilling the agency’s mission or optimizing research  
797 in substance use, abuse, and addiction. All members strongly agree that some form of  
798 reorganization is required in order to effectively capitalize upon existing and potential synergies,  
799 address scientific opportunities, meet public health needs, and train the next generation of  
800 investigators. Second, either reorganization strategy has the potential to improve and advance the  
801 conduct of SUAA research at the agency. To ensure either option’s success, it will be critical that  
802 all parties involved address the potential challenges associated with each during the  
803 implementation process. Finally, regardless of the reorganization strategy implemented, the  
804 immediate and long-term success of either option will critically depend upon leadership at all  
805 levels: the NIH Director, participating IC Directors, and participating staff. Support and  
806 oversight from the NIH Director will aid the reorganization by signaling a firm commitment to  
807 integrating addiction research and by holding the steering committee accountable for its work.  
808

809  
810 **Appendix A**  
811 **Speakers and Dates**  
812

813  
814 **April 27-28, 2009**  
815

- 816 • Lawrence A. Tabak, D.D.S., Ph.D., Director, National Institute of Dental and  
817 Craniofacial Research and Acting Deputy Director, NIH
- 818 • Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, NIH
- 819 • Kenneth R. Warren, Ph.D., Acting Director, National Institute on Alcohol Abuse and  
820 Alcoholism

821  
822 **September 23, 2009**  
823

824 ***Prevention Specialists***

- 825 • Nancy Freudenthal, First Lady of Wyoming
- 826 • Sheppard Kellam, M.D., Professor Emeritus, Johns Hopkins Bloomberg School of Public  
827 Health

828  
829 ***Treatment Providers***

- 830 • Herbert D. Kleber, M.D., Professor of Psychiatry and Director, Division on Substance  
831 Abuse, Columbia University College of Physicians and Surgeons and New York State  
832 Psychiatric Institute
- 833 • Marc A. Schuckit, M.D., Professor of Psychiatry, University of California, San Diego;  
834 Director, Alcohol Research Center and the Alcohol & Drug Treatment Program, VA San  
835 Diego Healthcare System

836  
837 ***Patient Advocates***

- 838 • Tom Donaldson, President, National Organization on Fetal Alcohol Syndrome
- 839 • Sue Rusche, President and CEO, National Families in Action; and Chief Architect, Parent  
840 Corps

841  
842 ***Public Policy Specialists***

- 843 • John Carnevale, Ph.D., Carnevale Associates, LLC

844  
845 ***Cellular and Molecular Science***

- 846 • Huda Akil, Ph.D., Professor and Senior Research Scientist, Department of Psychiatry;  
847 and Co-Director, Mental Health Research Institute, University of Michigan
- 848 • R. Adron Harris, Ph.D., June and J. Virgil Waggoner Chair in Molecular Biology and  
849 Director, Waggoner Center for Alcohol and Addiction Research University of Texas at  
850 Austin

851  
852 ***Systems Science***  
853

- 854 • Michael Charness, M.D., Chief of Staff, VA Boston Healthcare System; Professor of  
855 Neurology and Faculty Associate Dean, Harvard Medical School; Assistant Dean, Boston  
856 University School of Medicine; and Scientific Director, NIAAA Consortium Initiative on  
857 Fetal Alcohol Spectrum Disorders

858  
859

860 ***Treatment/Relapse***

- 861 • Thomas R. Kosten, M.D., Waggoner Chair and Professor of Psychiatry, Pharmacology,  
862 and Neuroscience, Baylor College of Medicine; and Research Director of the VA  
863 National Substance Use Disorders Quality Enhancement Research Initiative
- 864 • Stephanie O'Malley, Ph.D., Professor and Director, Division of Substance Abuse  
865 Research in the Department of Psychiatry, Yale University School of Medicine; and  
866 Director of Addiction Services, Connecticut Mental Health Center

867

868 ***Consequences***

- 869 • Scott Friedman, M.D., Chief and Senior Attending Physician, Division of Liver Diseases,  
870 Mount Sinai School of Medicine
- 871 • David Vlahov, Ph.D., R.N., Director for the Center for Urban Epidemiologic Studies,  
872 New York Academy of Medicine; Professor of Clinical Epidemiology, Mailman School  
873 of Public Health at Columbia University; and Adjunct Professor of Epidemiology, Johns  
874 Hopkins Bloomberg School of Public Health

875

876 ***Policy Research***

- 877 • Thomas Greenfield, Ph.D.
- 878 • Scientific Director, Alcohol Research Group, Public Health Institute; and Adjunct  
879 Clinical Faculty, Clinical Services Research Program, Department of Psychiatry,  
880 University of California, San Francisco
- 881 • David Rosenbloom, Ph.D., President and CEO, National Center on Addiction and  
882 Substance Abuse, Columbia University

883

884 **October 14, 2009**

885

886 ***Judicial System***

- 887 • Linda Chezem, J.D. Professor, Youth Development and Agricultural Education, College  
888 of Agriculture, Purdue University
- 889 • Pamela Rodriguez President, TASC, Inc.,

890

891 ***Academia***

- 892 • Steven E. Hyman, M.D., Provost, Harvard University; Professor of Neurobiology,  
893 Harvard Medical School
- 894 • John H. Krystal, M.D., Deputy Chairman of Research, Department of Psychiatry, Yale  
895 University; Director, Center for the Translational Neuroscience of Alcoholism, National  
896 Institute on Alcohol Abuse and Alcoholism; Director, Alcohol Research Center and  
897 Clinical Neuroscience Division, National Center for PTSD, U.S. Department of Veterans  
898 Affairs

899

900 **Industry**

- 901 • Bankole Johnson, D.Sc., M.D., Ph.D., M.Phil., F.R.C.Psych., Chair of Psychiatric  
902 Medicine, Department of Psychiatry and Neurobehavioral Sciences, University of  
903 Virginia
- 904 • Steven M. Paul, M.D. Executive Vice President, Science and Technology; President,  
905 Lilly Research Laboratories, Eli Lilly and Company

906

907 **December 22, 2009**

908

- 909 • Enoch Gordis, M.D. (Director of NIAAA from 1986 – 2001)  
910 • Alan Leshner, Ph.D. (Director of NIDA from 1994 through 2001)  
911 • Ting-Kai Li, M.D. (Director of NIAAA from 2002 through 2008)

912

913 **March 10, 2010**

914

- 915 • Hal G. Rainey, Ph.D., M.A., Alumni Foundation Distinguished Professor and Ph.D.  
916 Director, Department of Public Administration and Policy, University of Georgia

917

918 **May 18, 2010**

919

920 **Members of the Community**

- 921 • John Carnevale, Ph.D., President, Carnevale Associates, LLC  
922 • Robert Carothers, Ph.D., J.D., Past President, University of Rhode Island  
923 • Mimi Fleury, Chair, Substance Abuse Manual Committee; and President and Co-  
924 Founder, Community of Concern, Inc.
- 925 • Nancy Freudenthal, First Lady of Wyoming  
926 • Flo Hilliard, M.S.H. Faculty Associate, Division of Continuing Studies, Professional  
927 Development and Applied Studies, University of Wisconsin-Madison  
928 • Sue Rusche Co-Founder, President, and CEO, National Families in Action; and Chief  
929 Architect, Parent Corps

930

931 **Specialists on Behavior, Treatment, and Prevention**

- 932 • Richard Catalano, Ph.D. Director, Social Development Research Group, School of Social  
933 Work, and Adjunct Professor of Education and Sociology, University of Washington
- 934 • Anita Smith Everett, M.D. Section Director and Assistant Professor, Community and  
935 General Psychiatry, Johns Hopkins Bayview Medical Center
- 936 • Peter Monti, Ph.D. Donald G. Millar Distinguished Professor of Alcohol and Addiction  
937 Studies, and Director, Center for Alcohol and Addiction Studies, Brown University
- 938 • Marc A. Schuckit, M.D. Distinguished Professor of Psychiatry, University of California,  
939 San Diego; and former Director, Alcohol Research Center and the Alcohol & Drug  
940 Treatment Program, Veterans Affairs San Diego Healthcare System

941

942 **Early Stage Investigators**

- 943 • Laura M. Bohn, Ph.D. Associate Professor, Departments of Molecular Therapeutics and  
944 Neuroscience, The Scripps Research Institute

- 945 • Adam C. Brooks, Ph.D. Research Scientist, Treatment Research Institute
- 946 • Sherry McKee, Ph.D. Director, Yale Behavioral Pharmacology Laboratory, and
- 947 Associate Professor of Psychiatry, Yale University
- 948 • Kimberly Nixon, Ph.D. Assistant Professor, Department of Pharmaceutical Sciences,
- 949 University of Kentucky
- 950 • NIH Grant Holders
- 951 • K. Michael Cummings, Ph.D., M.P.H. Chair, Department of Health Behavior, Roswell
- 952 Park Cancer Institute, and Professor, Department of Social and Preventive Medicine,
- 953 School of Public Health and Health Professions, University at Buffalo, The State
- 954 University of New York
- 955 • Bankole Johnson, D.Sc., M.D., Ph.D., M.Phil., F.R.C.Psych. Chair of Psychiatric
- 956 Medicine, Department of Psychiatry and Neurobehavioral Sciences, University of
- 957 Virginia
- 958 • Peter W. Kalivas, Ph.D. Professor and Co-Chair, Department of Neurosciences, Medical
- 959 University of South Carolina
- 960 • Charles P. O'Brien, M.D., Ph.D. Kenneth Appel Professor, Department of Psychiatry,
- 961 School of Medicine, The Mahoney Institute of Neurological Sciences, University of
- 962 Pennsylvania
- 963 • Adolf Pfefferbaum, M.D. Professor Emeritus, Department of Psychiatry and Behavioral
- 964 Sciences, Stanford University; Senior Administrative Psychiatrist, California Division of
- 965 Juvenile Justice; and Director, Neuroscience Program, SRI International
- 966 • Marc N. Potenza, M.D., Ph.D. Director, Problem Gambling Clinic; Director, Women and
- 967 Addictive Disorders Core, Women's Health Research; and Associate Professor of
- 968 Psychiatry and Child Study, Division of Substance Abuse, Yale University
- 969 • Cary R. Savage, Ph.D. Director, Functional MRI, Hoglund Brain Imaging Center, and
- 970 Professor, Department of Psychiatry and Behavioral Sciences, University of Kansas
- 971 Medical Center

972

973 ***Reflections From Current NIDA and NIAAA Directors***

- 974 • Nora D. Volkow, M.D. Director, National Institute on Drug Abuse
- 975 • Kenneth R. Warren, Ph.D. Acting Director, National Institute on Alcohol Abuse and
- 976 Alcoholism

977

978

979



980  
981 **Appendix B**  
982 **NIAAA Advisory Council Resolution**  
983

984  
985 *Resolution of Council passed on 2-4-10: 14 in favor; 0 opposed; 1 abstention.*  
986

987 The NIAAA Council strongly advises against an NIH reorganization that eliminates NIAAA as  
988 an independent Institute. We encourage increased collaboration across NIH Institutes and  
989 Centers to strengthen research on the use, abuse, and addiction to alcohol, tobacco, drugs of  
990 abuse, and high-fat and high-sugar foods. We also advocate increased collaboration to improve  
991 the diagnosis and treatment of the co-morbid mental health disorders associated with addiction.  
992

993 We wish to emphasize the following points in support of our position:  
994

995 **1. Alcohol is the only legal, socially acceptable, recreational drug; research on alcohol**  
996 **requires a different approach than research on drugs of abuse.**

997 Alcohol use disorders (AUDs) arise in the context of widespread, healthy, social drinking. More  
998 than 120 million Americans use alcohol recreationally with clear social and health benefits,  
999 including a reduced risk for heart disease and stroke. In contrast, the recreational use of  
1000 inhalants, nicotine, prescription drugs or illegal drugs is never socially acceptable or medically  
1001 advisable. An important goal of alcohol research is to inform public policy and education to help  
1002 limit drinking to safe levels in healthy adults and to encourage abstinence during pregnancy and  
1003 before the age of 21. Abstinence or prohibition, the fundamental model of prevention for most  
1004 drugs of abuse, is a proven, failed policy for the prevention of AUDs in adults, precisely because  
1005 the healthy use of alcohol is ubiquitous in society. Thus, research in areas of prevention and  
1006 social policy differs markedly for alcohol versus illicit drugs. The merger of NIDA and NIAAA  
1007 would blur the clear and distinct public health message of each Institute, and weaken crucial  
1008 alcohol-related public policy research.  
1009

1010 **2. Alcohol use disorders are different than drug addiction.**

1011 The genetics of alcoholism differs from the genetics of drug addiction. Prospective studies have  
1012 shown that the sons of alcoholics are at greater risk for alcoholism than for drug dependence.  
1013 Furthermore, a number of medications effective in the treatment of AUDs are not useful for the  
1014 treatment of drug dependence and vice versa, suggesting that divergent pathways of medications  
1015 development must be followed to address fundamental differences in the underlying  
1016 pathophysiology of these disorders.  
1017

1018 **3. Alcohol misuse disorders produce enormous medical, economic, and social costs.**

1019 Even if most individuals recover spontaneously from AUDs, their misuse of alcohol results in  
1020 enormous medical, economic, and societal costs. AUDs cost the nation \$235 billion annually,  
1021 nearly 80% more than the costs related to all other addictive drugs. AUDs result annually in  
1022 more than 80,000 deaths, approximately 1/3 of all fatal car crashes, 1/2 of all homicides, 1/3 of  
1023 all suicides, and 1/3 of all hospital admissions. Alcohol damages virtually every organ system.  
1024 Fetal alcohol spectrum disorders are the most common non-genetic cause of mental and  
1025 cognitive impairment, affecting up to 1 in 100 live births. Alcoholic liver disease, alone or in

1026 combination with viral hepatitis, is the most prevalent form of chronic liver disease in the  
1027 Western world. Most research on fetal alcohol spectrum disorders, alcoholic liver disease, and  
1028 alcohol-related organ toxicity is funded by NIAAA.  
1029

1030 **4. Much of the public health burden of alcohol use disorders is caused by the non-addictive**  
1031 **use of alcohol.**

1032 The non-addictive use of alcohol accounts for much of the public health burden related to AUDs,  
1033 including that related to fetal alcohol spectrum disorders, fatal car crashes, accidents, and  
1034 homicides. On college campuses alone, alcohol use results annually in almost 2000 deaths,  
1035 100,000 sexual assaults, 600,000 injuries, and 700,000 assaults. For most college students,  
1036 problematic drinking and its associated morbidity will not be solved by novel  
1037 pharmacotherapies. Rather, psychosocial and public policy research championed by NIAAA is  
1038 critical in the effort to reduce harmful college drinking.  
1039

1040 **5. The existence of certain commonalities in the brain pathways that mediate the rewarding**  
1041 **effects of alcohol and other drugs of abuse does not justify the merger of NIAAA and**  
1042 **NIDA.**

1043 Reward systems in the brain govern many motivated behaviors, including eating, drinking,  
1044 romantic courtship, sex, music appreciation, and diverse positive social interactions. The fact that  
1045 these neural circuits also contribute to the rewarding effects of alcohol and drugs of abuse does  
1046 not justify merging NIAAA and NIDA. Likewise, the fact that dopamine is an important  
1047 neurotransmitter in signaling reward associated with myriad motivational stimuli does not  
1048 provide a strong rationale for merging Institutes. Dopamine systems are perturbed in Parkinson  
1049 disease, schizophrenia, and childhood dystonia, yet no mega-merger is proposed for NINDS,  
1050 NICHD, NIMH, NIAAA, and NIDA. In the same way, we do not advocate the merger of  
1051 NIDDK, NIAAA and NIDA to study those elements of food addictions, alcoholism, and drug  
1052 addiction that share similar brain pathways, or the merger of NIDA or NIAAA with NIMH to  
1053 study psychiatric co-morbidity. However, we do advocate enhanced collaboration among these  
1054 Institutes to better understand how these disorders interact and overlap.  
1055

1056 **6. Most individuals with alcohol use disorders do not abuse other drugs.**

1057 NIAAA's study of more than 43,000 subjects demonstrated that most individuals with AUDs do  
1058 not have mental health disorders and do not abuse other drugs. Although most individuals who  
1059 abuse drugs also have AUDs, this subgroup comprises a minority of individuals with AUDs and  
1060 contributes to a small share of the public health burden associated with AUDs. The large size of  
1061 the population with AUDs who don't abuse other drugs and the enormous public health burden  
1062 of their illness justify NIAAA's focused approach to research on AUDs, separate from drug  
1063 dependence. The combined abuse of alcohol and drugs can be addressed through enhanced  
1064 collaboration between NIAAA and NIDA. Likewise, the subgroup of individuals with AUDs and  
1065 mental health disorders can be studied through enhanced collaboration between NIAAA and  
1066 NIMH.  
1067

1068 **7. Alcohol differs from other drugs of abuse in the degree to which heavy use damages the**  
1069 **brain and other organs.**

1070 Alcohol is particularly toxic to the brain and myriad organ systems, as well as to the developing  
1071 fetus. The neurological disorders that result from alcohol neurotoxicity and concomitant

1072 malnutrition constitute a large and important public health problem. Alcohol damages multiple  
1073 organ systems through common mechanisms of toxicity, including oxidative stress, the  
1074 disruption of critical cell signaling systems, and the generation of toxic metabolites, cytokines,  
1075 and chemokines. The coordinated study of these multiple organ toxicities is best suited to a  
1076 single alcohol Institute.

1077  
1078 **8. A systems approach is essential to the study of alcohol's beneficial and adverse effects**

1079 Alcohol affects the entire body, enhancing cardiovascular health with moderate use, and  
1080 damaging multiple organs with heavy use. Alcohol-induced injury in one organ system, such as  
1081 the gut, liver, or immune system, is inexorably linked to alterations in the structure and function  
1082 of others, such as the brain. NIAAA recognizes that a systems biology approach is essential to  
1083 study the universe of alcohol's beneficial and harmful interconnected effects on the brain and  
1084 other organ systems. The merger of NIAAA with NIDA to form a new Institute focused on  
1085 addiction would orphan and dissociate critical programs focused on alcohol and cardiovascular  
1086 health, liver disease, pancreatitis, fetal alcohol spectrum disorders, immune disorders, myopathy,  
1087 neuropathy, and brain disorders. Alcohol research clearly benefits greatly from the  
1088 organizational integrity of a single Institute that focuses on all aspects of alcohol.

1089  
1090 **9. A merger will sacrifice the diverse approaches of two Institutes to addiction research.**

1091 The cornerstone of health research in the United States is the investigator initiated grant and the  
1092 thousands of ideas generated by independent investigators. Even at the level of NIH Institutes,  
1093 there are advantages to diversity in the evolution of scientific ideas. NIAAA has fostered an agile  
1094 approach to medications development that benefits from its focus on a single drug, alcohol, and  
1095 an integration of basic science research, translational research, and clinical trials using patients at  
1096 an early stage of disease development. The product of this research is more than a dozen  
1097 medications approved or under investigation for the treatment of AUDs. NIDA utilizes a clinical  
1098 trials network that tests medications for diverse drugs of abuse in individuals with more  
1099 advanced disease who are often recruited from the criminal justice system. The creation of a  
1100 single, large Institute under the direction of a single director risks losing the diversity of  
1101 approaches to the development of treatments for these conditions and the agility of NIAAA, as a  
1102 small Institute, to adapt quickly in response to scientific opportunities.

1103  
1104 **10. The loss of an independent NIAAA will damage NIH's initiative on improving global**  
1105 **health.** NIAAA is a leader among NIH Institutes in conducting global health initiatives. Foreign  
1106 countries that cannot afford an alcohol Institute have looked to NIAAA for guidance in setting  
1107 policy on the use and abuse of alcohol. A decision to abolish NIAAA would send a message to  
1108 the global community that the United States devalues the effort to coordinate research and policy  
1109 related to alcohol, the fifth leading cause of global death and disability.

1110  
1111 **11. The loss of an independent NIH Institute dedicated to alcohol research will discourage**  
1112 **young scientists from entering the field.**

1113 NIAAA's emergence as an Institute brought the importance of alcohol-related health problems to  
1114 national attention and signaled to researchers that alcohol research is an important public health  
1115 endeavor and area of scientific inquiry. NIAAA has attracted some of the best and brightest  
1116 investigators to the field. The loss of an independent Institute devoted to research on alcohol  
1117 abuse and alcoholism will deter the recruitment of new researchers to the field.

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**12. What we stand to lose through the merger of NIAAA and NIDA is far more than what we stand to gain. What we stand to gain through merger can be accomplished through alternative approaches, including enhanced collaboration between NIAAA and NIDA.**

Mergers of large organizations are traumatic, destabilizing, time-consuming, and costly; therefore, we stand to lose time, personnel, resources, and mission focus. Mergers often result in organizations that are too large, inflexible, and unwieldy to respond quickly to changing opportunities and sacrifice the diversity of their parent organizations. Dissolving NIAAA into an Institute on addiction or drug use and abuse will compromise the integrated study of genetics, cell biology, organ systems, psychology, social systems, and public policy that characterizes NIAAA's coordinated approach to one of America's most important public health burdens. On the other hand, it is not clear what we stand to gain, either scientifically or organizationally, through a merger of NIDA and NIAAA that could not be accomplished through enhanced collaborations between the two Institutes and across NIH.

1134 **Appendix C**  
1135 **NIDA Advisory Council Resolution**  
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1137  
1138 *Resolution of Council passed on 3-1-10: 15 “Approve”; 0 “Reject”.*  
1139

1140 **Whereas**, the National Advisory Council of the National Institute on Drug Abuse (NIDA) is  
1141 charged with advising and making recommendations to the Secretary of Health and Human  
1142 Services and the Director, National Institute on Drug Abuse on matters related to the activities  
1143 carried out by and through the Institute and the policies respecting these activities,  
1144

1145 **And Whereas**, a drug is defined as an abusable chemical substance that alters living processes;  
1146 and this includes cocaine, heroin, alcohol, marijuana, and other addictive drugs;  
1147

1148 **And Whereas**, epidemiologic studies show that persons addicted to one drug are very vulnerable  
1149 to addiction to other drugs;  
1150

1151 **And Whereas**, drug abuse exacts a tremendous toll on US society annually including an  
1152 economic burden of \$600 billion in health, crime-related costs, and losses in productivity as well  
1153 as the premature deaths of more than 500,000 Americans;  
1154

1155 **And Whereas**, scientific research shows extensive biological across-drug commonalities in the  
1156 causes, mechanisms, prevention, and treatment of drug addiction, regardless of which particular  
1157 drug is considered;  
1158

1159 **And Whereas**, a unified research focus on underlying causes, mechanisms, prevention, and  
1160 treatment of drug addiction, regardless of the particular drug involved, is most likely to clarify  
1161 similarities and differences among addictive drugs, to advance scientific knowledge, and to  
1162 improve the public health;  
1163

1164  
1165 **We resolve** that the benefits derived through combining the research efforts for all drug use and  
1166 addiction into a single entity outweigh the benefits in continuing the status quo.  
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1168  
1169 **Therefore, the National Advisory Council of the National Institute on Drug Abuse advises ...**  
1170

1171 That the Secretary of Health and Human Services and Director of NIDA vigorously should  
1172 support efforts to combine and focus within a single NIH Institute research on the causes,  
1173 mechanisms, prevention, and treatment of the non-medical use of, and addiction to, all addictive  
1174 drugs, .  
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