DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Bethesda, Maryland 20892

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Harold T. Shapiro, Ph.D.
Chairman, Committee on the Organizational Structure of NIH
Woodrow Wilson School of Public and International Affairs
Princeton University
355 Wallace Hall
Princeton, New Jersey 08544

Dear Dr. Shapiro:

I am sending the enclosed report at the request of the National Institutes of Health (NIH) Council of Public Representatives (COPR). This report is its response to the Institute of Medicine's report *Enhancing the Vitality of the NIH: Organizational Change to Meet New Challenges*. This January 2004 COPR report follows the December 2002 COPR report submitted prior to the Institute of Medicine's final deliberations.

COPR is a forum for advising the NIH Director on issues affecting the broad development of NIH policy, programs, and research goals. It also advises and assists the NIH Director in enhancing public participation in NIH activities, increasing public understanding of the NIH, and bringing important matters of public interest forward for discussion in public settings. The COPR membership comprises a variety of backgrounds, cultures, geographic origins; and its members share a vital interest in the work of the NIH. The enclosed report therefore represents COPR's independent conclusions and recommendations regarding the organizational structure and management of the NIH.

I trust you and the Committee will find this report helpful and of interest to your efforts.

Sincerely,

Elias A. Zerhouni, M.D.
Director

Enclosure

cc: Frances Sharples, Ph.D.
Bruce Alberts, Ph.D
Harvey Fineberg, M.D., Ph.D

The NIH Council of Public Representatives (COPR)
RESPONSE TO THE NRC/IOM REPORT: Enhancing the Vitality of the National Institutes of Health: *Organizational Changes to Meet New Challenges*

Report to:
Elias A. Zerhouni, M.D.,
Director, National Institutes of Health
From:
NIH Director's Council of Public Representatives (COPR)

December 1, 2003

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INTRODUCTION

In 2001, Congress mandated a study of the organizational structure of the NIH to determine "whether the current organization and structure of NIH are optimally configured for the scientific needs of the twenty-first century." The National Research Council (NRC) and the IOM (Institute of Medicine) of the National Academies undertook the study and formed the Committee on the Organizational Structure of the National Institutes of Health ("IOM Committee").

Chaired by Dr. Harold Shapiro, the IOM Committee focused on whether there might be any "significant organizational changes…that would allow NIH to be even more successful in the future" in supporting the research essential to improving human health. The IOM Committee conducted an extensive analysis of what it characterized as the complex, highly decentralized, $27 billion per year structure that the NIH has evolved into since it was founded in the late 19th century.

The Council of Public Representatives (COPR) was created as a public voice of the American people, in the broadest and least encumbered sense, to the Director of the National Institutes of Health (NIH). In December 2002, partially stimulated by the NRC/IOM study, the COPR analyzed a number of aspects of the structure and function of the NIH, specifically from the public perspective. The Council's conclusions were contained in the "Report on the

Organizational Structure and Management of the NIH" ("COPR December 2002 Report"), which was sent to the Director, who forwarded it to the IOM Committee for its consideration.

In July 2003 the IOM Committee released its report entitled "*Enhancing the Vitality of the National Institutes of Health: Organizational Changes to Meet New Challenges*" (the "NRC/IOM Report"), which represented a detailed and independent examination of the NIH. The NRC/IOM report contained fourteen specific recommendations:

1. Centralization of Management Functions
2. Establish a Public Process for Changing the Number of NIH Institutes or Centers
3. Strengthen Clinical Research
4. Increase Trans-NIH Strategic Planning and Funding
5. Strengthen the NIH Office of the Director (OD)
6. Establish a Process for Creating New OD Offices and Programs
7. Create a Director's "Special Projects" Program
8. Promote Innovation and Risk Taking in the Intramural Research Program (IRP)
9. Standardize Data Management Systems
10. Set Term Limits for IC Directors and Establish a IC Director Review Process
11. Set Term Limits for the NIH Director
12. Reconsider the Status of the National Cancer Institute
13. Reform Advisory Council Activity and Membership Criteria
14. Increase Funding for Research Management and Support (RMS)

In this report, prepared for the NIH Director, the COPR responds to these recommendations, from the public perspective. Although we are confining our remarks specifically to the recommendations, we note three important issues:

1. We are heartened that that IOM Committee found no compelling reason to suggest an alternative organizational structure for NIH, and that the current organizational structure represents a fundamentally useful response to the legitimate demands made by NIH's various constituencies.
2. We raise the question: What is the public process for introducing the NRC/IOM Report to the public?
3. Will there be opportunity for the public to provide input on these recommendations beyond COPR's response?

DISCUSSION

The IOM Report clearly reflects some of the core issues that COPR raised in its December 2002 Report. As to the resulting 14 recommendations in the final NRC/IOM Report, we have identified 6 of the recommendations as priority areas from the public's perspective. We also provide comment on 3 additional recommendations and include specific comment on a priority issue for the COPR, not directly reflected in the NRC/IOM Report recommendations, all in the spirit of the IOM Committee's mandate "to be of some practical assistance to all who wish NIH to continue to be an effective – indeed, outstanding – organization."

Top Priorities

Recommendation 4. Increase Trans-NIH Strategic Planning and Funding

We strongly support the concept of the Institute and Centers' (ICs) designating funding toward centrally defined research priorities. In the implementation of this process, some interested parties may view the contributions on the part of the IC's as a reduction in the ICs' individual research capacities. NIH may need to make a concerted effort to communicate that this initiative is not "taking" something from IC budgets, but rather it is finding a "convergence of research priorities," and of developing a trans-institute process for moving forward into the new century

Recommendation 5. Strengthen the NIH Office of the Director (OD)

The Office of the Director must be equipped with the tools necessary to facilitate and integrate research on a trans-NIH basis. The budget of the OD has not kept pace with the growth of the overall NIH research organization, even as the OD has been expected to take on added responsibilities that accompany the growth. The OD needs additional funds if the director's office is to function properly and lead NIH as it addresses the research needs of the future. (paraphrase of COPR December Report page 5).

Recommendation 7. Create a Director's "Special Projects" Program

We strongly support this mechanism for funding "the initiation of high-risk, exceptionally innovative research projects offering high potential payoff" (NRC/IOM Report page 77). This comports with our belief that the OD should have discretion to allocate money based on "shifting priorities and emerging opportunities" (COPR December Report page 5).

Recommendation 8. Promote Innovation and Risk Taking in the Intramural Research Program (IRP)

In our opinion the intramural research should complement extramural research programs. We should strongly encourage the investigators to test innovative hypotheses that involve intellectual scientific risk. We also strongly support a multi-disciplinary approach to biomedical research and agree that this process requires "substantial input from the scientific community and the public" (NRC/IOM Report page 81).

Recommendation 9. Standardize Data Management Systems

We acknowledge that this will likely be a long and costly process, but strongly believe that the NIH must establish single, unitary standards for data collection and integration that apply to all NIH-sponsored research activity. Failure to implement standardization, and even delay in doing so, carries a price that is measured in deferred development of therapy and increased risk in clinical trials that ultimately threaten patient care and improvements for the health of Americans (COPR December Report page 6). Moreover, we also regard this as an integral component of the NIH Roadmap for Medical Research (Roadmap).

Recommendation 14. Increase Funding for Research Management and Support (RMS)

We consider the need for administrative funding to be an important area, and support the proposition that if Congress is going to impose a mandate on the NIH, it should then fund at the appropriate level to support the enterprise. We view this funding as being separate from recommendation number 5, and therefore expect that funding for RMS will not reduce the existing budget of the OD.

Secondary Priorities

Recommendation 2. Establish a Public Process for Changing the Number of NIH Institutes or Centers

We heartily endorse the idea of establishing a public process to "evaluate scientific needs, opportunities, and consequences" of proposed changes in the number of institutes and centers (NRC/IOM Report page 6), but we emphasize our view, expressed in the COPR December 2002 Report (pages 3 and 4), that the public process should be established *to explore* not only *changing* the number of institutes and centers, but also *consolidating* them. The emphasize that public input should be actively solicited, as early as possible, through a number of notification avenues and that the window of opportunity for when the public is engaged in the discussion should be open and transparent.

Recommendation 6. Establish a Process for Creating New OD Offices and Programs

We note that this recommendation, as written, does not mention a *public* process, although we are aware that the IOM Committee stated, "The public process for evaluating proposals to create organizational units described in Chapter 4 [regarding changing the number of ICs] should also be applied to programmatic offices in the OD" (NRC/IOM Report page 82). At present there is no defined process for creating "Offices," which can be triggered by focal pressure from a scientific or public health standpoint. We endorse the idea of establishing a public process to "evaluate scientific needs, opportunities, and consequences" of proposed changes in the number of offices in the Office of the Director.

We recommend that, similar to the process we suggested for recommendation Number 2 (supra), when discussion is initiated on this issue, a public process be established to explore the creation or consolidation of OD offices and programs. In addition, we urge that an appropriate trigger for initiating this public process be clearly identified and initiated at the earliest point in the action process. The emphasize that public input should be actively solicited, as early as possible, through a number of notification avenues and that the window of opportunity for when the pubic is engaged in the discussion should be open and transparent.

Recommendation 13a. Advisory Council Activity and Membership Criteria

We provide comment on aspects of this recommendation and include specific comment on a priority issue for the COPR, not directly reflected in the NRC/IOM Report Recommendation 13, but directly related to the topic of advisory council membership and activity.

We firmly believe that the principle of empowering patients and the public as significant partners in the research process is integral to enhancing transparency in the research enterprise and to the continuing success of the NIH. Public members of Advisory Councils need to be actively involved in the priority setting process and be frequently consulted to provide the public perspective. We believe that clear identification of public members on each Institute and Center Advisory Council and a common definition of their roles are essential to promoting this partnership and transparency in the research enterprise.

We strongly recommend the following:

1. Public members of IC advisory councils are clearly identifiable;

2. Public members of IC advisory councils are appointed for the purpose of bringing the public's perspective to the council and the institute;

3. Public members of IC advisory councils are trained and educated, with their peers *(other public members)* so they can better serve in their role as a significant partner in the research process.

4. All appointments to advisory councils should be based solely on a person's scientific or clinical expertise or his or her commitment to and involvement in issues of relevance to the mission of the Institute or Center, while taking diversity into account.

Remaining Recommendations

In preparing this report, we considered all of the recommendations put forth by the IOM Committee. We do not at this time have any comment on the remaining recommendations (Numbers 1, 3, 10, 11 and 12), but our lack of comment should not be construed as indicating either acceptance or rejection. Rather, we have focused our attention on the 9 recommendations that we feel should be emphasized from the public standpoint.

CONCLUSION

In summary, our prioritization of the recommendations reflects our continuing belief, as stated in our COPR December 2002 Report, that “the goal in changing the existing framework of the NIH should be to create mechanisms that embrace and are responsive to all constituencies, including the American public, as partners in the research process; that facilitate collaborative interactions between those partners; and that are more open to change and new ideas.”