NIH SCIENTIFIC MANAGEMENT REVIEW BOARD

November 10, 2010

MEETING - SUMMARY

Board Members Present via Teleconference:

Norman R. Augustine, Chair
Jeremy Berg, Ph.D.
Gail H. Cassell, Ph.D.
Anthony Fauci, M.D.
The Honorable Daniel Goldin
Eric Green, M.D., Ph.D.
Richard Hodes, M.D.
Stephen Katz, M.D., Ph.D.
Thomas Kelly, M.D., Ph.D.
Deborah Powell, M.D.
William Roper, M.D., M.P.H.
Harold Varmus, M.D.
Huda Zoghbi, M.D.

Ex-Officio Members Present:
Lawrence Tabak, D.D.S., Ph.D. (on behalf of Francis S. Collins, M.D., Ph.D.)

Staff Present:
Amy P. Patterson, M.D., Executive Secretary

Opening Remarks

Scientific Management Review Board (SMRB) Chair Norman Augustine opened the meeting and welcomed Dr. Eric Green, Director of the National Human Genome Research Institute (NHGRI), to the Board. Dr. Green has replaced Dr. Lawrence Tabak, who accepted the position of Principal Deputy Director of the National Institutes of Health (NIH).

Mr. Augustine updated the Board on the status of ongoing SMRB activities:

- The SMRB Report on Substance Use, Abuse, and Addiction (SUAA) Research at NIH was updated to reflect the proceedings of the September SMRB meeting (recommending the creation of a new SUAA institute and the merger of NIDA and NIAAA into this new institute). The revised report has been approved by all SMRB members and should be transmitted to NIH Director Francis Collins in the near future.

- The Translational Medicine and Therapeutics (TMAT) Working Group will update the Board of its findings during this teleconference. The Working Group will take member and public comments into account as they draft their final report, which will be presented for review by the next SMRB meeting on December 7-8, 2010. If the Board agrees with

the TMAT report, it will be transmitted to Dr. Collins very soon after the December meeting. This accelerated pace will allow the TMAT recommendations to be included in plans for the Fiscal Year 2012 budget.

- The Intramural Research Program (IRP) Working Group Report on the NIH Clinical Center will also be brought before the Board for a vote at the meeting in December. A vote on the report was tabled at the previous SMRB meeting in September in order to allow the TMAT Working Group to develop its recommendations, which might have an effect on the Board's recommendations regarding the Clinical Center.

Dr. Amy Patterson reminded the Board of the NIH Conflict of Interest Policy.

Presentation of Translational Medicine and Therapeutics (TMAT) Working Group Recommendations

William Roper, M.D., M.P.H.
Member, Translational Medicine and Therapeutics Working Group

Dr. William Roper delivered the TMAT Working Group's findings and recommendations, which were summarized on PowerPoint slides made available to all meeting participants. The TMAT Working Group was charged with identifying the attributes, activities, and functional capabilities of a TMAT program at NIH; broadly assessing relevant programs for inclusion and how they could be organized; and considering how NIH could leverage existing resources and implement the newly-authorized Cures Acceleration Network (CAN). Dr. Roper clarified that the term "program" is meant to describe a set of activities, not an organizational unit.

Dr. Roper stated that the TMAT Working Group had determined that new challenges and opportunities in the field of therapeutics development warranted reorganization of some programs at NIH. The group identified the functions and attributes that a reorganized translational medicine program at NIH should have. The program should:

- Conduct, support, and strengthen translational research;
- Provide a central locus for information on and access to resources, tools, and expertise related to TMAT research;
- Serve as a catalyst and convener for collaborative interactions and partnerships;
- Expand the pre-competitive space;
- Support translational research workforce and training for investigators; and
- Enhance communication with and among all stakeholders.

To accomplish these goals, the group recommended the creation of a new translation-focused center, which would house programs such as the Therapeutics for Rare and Neglected Diseases (TRND) program, NIH Rapid Access to Interventional Development (RAID) program, Molecular Libraries Program, and new NIH-FDA partnerships. In addition, the group considered inclusion of the NIH Clinical Center and the Clinical and Translational Science Awards (CTSA)

program and met with their respective directors, Drs. John Gallin and Barbara Alving. The TMAT Working Group concluded that the CTSAs were ideally suited for inclusion in the new center, but that the Clinical Center, which houses significant non-translational research for NIH institutes and centers (ICs), should remain independent but have strong ties with the new center.

Dr. Roper reported that the TMAT Working Group concurred with the IRP Working Group's recommended changes for the NIH Clinical Center. The recommendations to make the Clinical Center a national resource, streamline the governance structure, and adjust the budget process are compatible with the TMAT recommendations. In fact, having strong functional ties to a new TMAT center may further strengthen the Clinical Center's role as a national resource.

Discussion

Dr. Tom Kelly inquired about the proposed center's relationship to TMAT extant programs in the NIH ICs. Dr. Roper clarified that TMAT activities currently being supported by ICs would not be relocated to the center. Drs. Tony Fauci and Harold Varmus agreed that TMAT-related programs within ICs should remain intact and should not be disrupted by the proposed center. Instead, an important role for the center should be to provide smaller ICs with opportunities to engage in TMAT research, including clinical trials, and to enable other entities to collaborate and work together more efficiently. The TMAT Working Group should articulate clearly the new center's relationship with existing TMAT programs in the ICs.

Dr. Gail Cassell suggested that the organization of TMAT research at NIH could model the structure established in large companies, where there are both disease-focused areas (i.e., ICs) that target unique areas of research and a central space (i.e., proposed center) in which the company can reduce redundancy, synergize, house common activities, and achieve economies of scale by centrally bargaining for contract services on behalf of all TMAT programs. Several parts of the therapeutics development process could be studied and streamlined in the center, including toxicology studies; absorption, distribution, metabolism, and excretion (ADME) studies; and pharmacokinetics studies. She also recommended that NIH carry out a thorough inventory of TMAT-related activities conducted and contracted by ICs in order to look for possible redundancies and discrepancies in pricing and efficiency. In addition, Dr. Cassell noted that a new center could lead NIH to interactions with the international TMAT research community.

The original impetus for considering TMAT research at NIH was, in part, the authorization for Cures Acceleration Network (CAN) included in the 2010 health care reform legislation. However, funds have not yet been appropriated for CAN. Dr. Steve Katz recommended that the TMAT Working Group remove any implication that the creation of the proposed center is dependent on the appropriation of funds for CAN.

Mr. Augustine asked the TMAT Working Group to address the National Academy of Science's concern about the fragmentation of NIH into so many different ICs.

Mr. Augustine reminded Board members of the upcoming SMRB meeting in Bethesda on December 7-8, 2010, and adjourned the meeting.

We certify that, to the best of our knowledge, the foregoing meeting minutes of the NIH Scientific Management Review Board are accurate and correct.

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Norman Augustine SMRB Chair	Amy Patterson SMRB Executive Secretary