Science Policy News
February 2011

ASIP Weighs Pathology's Role in the New National Center for Advancing Translational Sciences

In April 2009, the National Institutes of Health's (NIH) Scientific Management Review Board (SMRB) held its first meeting. Composed of representatives from the NIH and the science community (see http://www.asip.org/paffairs/NIH SMRBCompositionPressRelease(Sept2008).pdf), the SMRB was established by the NIH Reform Act of 2006 to advise appropriate Department of Health and Human Services (DHHS) and NIH officials on the use of its organizational authorities to:

- Establish/abolish national research institutes;
- Reorganize offices within the Office of the NIH Director; and
- Reorganize divisions, centers, or other administrative units within an NIH national institute or center.

In May 2010, newly installed NIH Director Francis Collins, MD, PhD requested the SMRB review and recommend to NIH how to integrate the numerous initiatives to translate basic research more rapidly into treatments and therapies. He noted that several components of the pipeline were already in place, such as:

- Molecular Libraries Initiative, including the NIH Chemical Genomics Center PubChem database
- Therapeutics for Rare and Neglected Diseases Program (TRND)
- Rapid Access to Interventional Development (RAID) Program
- NIH Clinical Center
- Clinical and Translational Science Awards (CTSAs)

At that time, Dr. Collins also acknowledged the potential role of the newly formed NIH-Food and Drug Administration (FDA) Joint Leadership Council (see http://www.nih.gov/news/health/feb2010/od-24.htm), as well as the potential impact of the Cures Acceleration Network (CAN), a competitive grant program at the NIH, which was authorized by Congress in healthcare reform legislation at $500 million (see http://www.asip.org/paffairs/CANLegislation(2009).pdf). He also noted reduced investments in research and development at pharmaceutical and biotechnology firms and the growing interest and expertise by academic institutions in assay development and high through-put screening.

In November 2010, the Translational Medicine and Therapeutics (TMAT) Working Group - a public-private group constituted from the SMRB and chaired by Arthur Rubenstein, MBBCh, Dean of the University of Pennsylvania School of Medicine - reported its major findings and recommendations. The specific charge of the Working Group was to identify the attributes, activities, and functional capabilities of an effective translational medicine program for advancing therapeutics development; to broadly

assess, from a high-level view, the NIH landscape for extant programs, networks, and centers for inclusion in this program and recommend their optimal organization; and in addressing its charge, to consider how the Department of Health and Human Services could leverage and organize a wide range of existing NIH resources and efficiently implement the CAN, assuming funds are appropriated for it.

In executing its charge, the TMAT Working Group considered current NIH-supported infrastructure, initiatives, and resources with direct relevance to the therapeutics development pipeline; methods to synergize, and avoid competition with, resources in the private sector; prior recommendations for strengthening the clinical and translational research enterprise at NIH, including recommendations of the IOM, and relevant lessons learned from industry, academia, non-profit organizations, etc.; and metrics and methodologies that could be used for evaluating the impact of changes in the organization and management of the therapeutic development program. See the complete TMAT Working Group presentation of its findings at *http://www.asip.org/paffairs/TMATPresentationNov2010.pdf*.

The principle recommendation of the TMAT Working Group was a proposal to create a National Center for Advancing Translational Sciences (NCATS), which would combine several existing programs, have a budget of at least $650 Million, and an objective of being operational by October 2011. Since NIH has reached its legal limit of 27 institutes and centers, and the merger of the National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism is not expected to happen until 2013, substantial reorganization of the National Center for Research Resources (NCRR) is anticipated to realize the proposed new NCATS.

According to answers to frequently asked questions about the NCATS (see http://feedback.nih.gov/index.php/ncats/faqs-ncats/), the functions and activities of the proposed Center would include:

- providing a visible, central locus for access to resources, tools, and expertise related to translational medicine;
- streamlining and improving the process of therapeutics development;
- serving as a catalyst, resource, and convener for collaborative interactions by supporting novel and innovative partnerships between multiple key stakeholders, including academia, government, industry, venture capitalists, and non-profit organizations;
- expanding the pre-competitive space by, among other things, enabling and providing incentives for greater sharing of scientific information and publication of negative results;
- supporting and strengthening translational medicine and therapeutics research, including providing access to services and resources for high-throughput screening, assay development, medicinal chemistry, and preclinical modeling;

- training translational research investigators; and enhancing communication among all stakeholders.

The proposed Center would be formed initially by integrating selected translational research programs now located within the NCRR, as well as the National Human Genome Research Institute (NHGRI), and the NIH Director's Common Fund. For example, the Clinical and Translational Science Awards (CTSA) program in NCRR would be included. Although the NCRR would likely be substantially reorganized, Dr. Collins states there are no plans to eliminate any of its programs.

To guide this major realignment of resources within NIH, Dr.Collins charged NIH Principal Deputy Director Lawrence A. Tabak, DDS, PhD, and National Institute of Child Health and Human Development Director Alan E. Guttmacher, MD, with heading a task force of NIH scientific experts. The task force will review existing programs recommended for inclusion in the new Center, assess the impact of the new Center on other relevant NIH programs (including those currently within the NCRR), and develop an implementation plan for establishing the new Center. More details about the task force's activities and timeline are expected soon, with formal reporting in Spring 2011.

In a recent article in Nature magazine (Vol. 468, p. 877), Dr. Collins commented, "I think some basic scientists will be quite excited about the opportunity to be more connected with the clinical benefits of their own discoveries." He further pointed to the national budgetary concerns as the probable driver of the push for more clinically relevant results in NIH research. Collins said, "…we should all be anxious about the overall budget right now with the expectation that dollars for biomedical research are going to be very hard to come by in the next year or two." In his Nature interview, Dr. Collins cited "a recent deluge of discoveries about the molecular pathogenesis of disease" and developments in molecular diagnostics as the key to new therapeutics.

ASIP supports concerns expressed by the Federation of American Societies for Experimental Biology in their December 6th letter to the SMRB (see http://www.asip.org/paffairs/FASEB_TMAT_ Letter_120610.pdf). However, ASIP is looking down the road to almost inevitable outcomes and hopes to catalyze these organizational changes into opportunities for Pathology to play a key role in advancing translational research. To that end, we urgently encourage ASIP members to consider how best to engage Pathology in NCATS or in educational endeavors supporting the development of basic scientists into clinical researchers.

If you have ideas you believe could be advanced through the resources of ASIP or if you simply want to be involved in as ASIP becomes engaged with the new NCATS

center, please email your comments and contact information to *asip@asip.org* by February 28, 2011.

This article can be seen in ASIP Pathways February 2011
http://www.asip.org/publications/newsletter/documents/ASIPPathwaysFeb2011.pdf

American Society for Investigative Pathology (ASIP)
9650 Rockville Pike, Suite E133, Bethesda, MD 20814 (USA)
Tel: +1 301 634 7130 | Fax: +1 301 634 7990 | Email: asip@asip.org