NIH Names Dr. Christopher Austin NCATS Director as NCATS and CAN Boards Meet

On September 14, Dr. Collins announced Christopher Austin, M.D. as NCATS Director. Dr. Austin, who previously served as Director of the NCATS Division of Pre-Clinical Innovation, received his medical degree from Harvard Medical School, where he performed a fellowship in developmental genetics of the retina. His first NIH grant was a Clinician-Scientist Award from the NEI. He succeeds NCATS Acting Director Thomas Insel, M.D., who continues to serve as the Director of the National Institute of Mental Health (NIMH).

The announcement was made at the first meeting of the NCATS Advisory Council, which was held jointly with the Cures Acceleration Network (CAN) Review Board—both entities were legislatively mandated CAN, which was authorized by the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) as an NIH program to move research quickly from “bench to bedside,” was put into NCATS when the latter was established as NIH’s centralized translational research authority in the FY2012 Appropriations Conference Agreement (P.L. 112-74). FY2012 CAN funding is $10 million, while overall NCATS funding is $575 million, driven primarily by the CTSA program.

In his opening comments, Dr. Insel noted that NCATS’s mission is to find a “different way of doing business” as it relates to the translation of basic research into diagnostics and therapeutics, which includes drugs, devices, and biologics. Although NCATS will serve as a catalyst for collaborations and can develop the infrastructure and support for clinical trials, it may not conduct these past Phase IIA. Specific goals include addressing the bottlenecks in translation, developing collaborations within and outside of the NIH, and engaging the advocacy community, especially as it relates to the NCATS portfolio.

Dr. Collins welcomed the attendees, noting their participation in this process of “disruptive innovation.” Rather than provide prepared remarks, he addressed questions about NCATS and CAN implementation. Highlights included:

- **NIH Budget and Sequestration:** Although noting that the President’s FY2013 budget request increases NCATS funding to $639 million from $575 million, driven primarily by a $40 million CAN increase, he was uncertain of the outcome of the appropriations process since Congress was preparing to vote on the six-month CR to fund the government in FY2013 at the FY2012 level. Regarding sequestration, he reiterated his comments that it would have a “devastating” impact on NIH, cutting its budget by $2.5 billion and primarily affecting new and competing grants.

- **Collaboration with Other DHHS Agencies:** Dr. Collins noted that DHHS “sister” agency, the Food and Drug Administration (FDA), was represented at the meeting by Commissioner Margaret Hamburg, M.D., who serves as an Ex-Officio member. Both Dr. Hamburg and Dr. Collins spoke about FDA’s crucial role in providing insights into the regulatory approval process, especially since NCATS’s purpose is to fast-track development of therapeutics. Dr. Collins noted the establishment in 2010 of a joint NIH/FDA Leadership Council which has already resulted in numerous collaborations. He also announced that he recently met at length with Centers for Medicare and Medicaid Services (CMS) Acting Administrator Marilyn Tavenner to engage the agency in identifying the data it needs to make coverage decisions for new therapies and to discuss cost-effectiveness and patient-centered outcomes research issues.

The remainder of the day’s meeting was spent discussing the CTSA and Pre-Clinical Innovation programs at NIH, seeking attendee comments about barriers in translational research.

NIH Council of Councils Meeting

At the September 5 NIH Council of Councils meeting, Dr. Collins announced Janine Austin Clayton, M.D. as the National Academy Director of Research on Women’s Health and the Associate Director of Research on Women’s Health. Formerly the Deputy Clinical Director at the NEI, Dr. Clayton has spoken on Capitol Hill on behalf of AEVER and the Vision 2020/USA initiative on aging eye research and the global burden of eye disease on women. At the meeting, Mae Gordon, Ph.D. (Washington University School of Medicine) concluded her three-year term as the National Advisory Eye Council’s (NAEC) representative to the Council. NEI will shortly announce the new NAEC representative.

Dr. Collins Briefs House Authorizers about NCATS, NIH’s “4 T’s”

On June 21, Dr. Collins testified before the House Energy and Commerce (E&C) Committee, which has authorizing oversight of NIH. Per the hearing notice, its intent was to review the implementation of the NIH Reform Act of 2006, the progress of NCATS implementation, and determination of NIH funding and research priorities.

In his testimony, Dr. Collins characterized the value of NIH investment in innovation through the four “T’s”—technology, translation, talent, and taxpayer return on investment. He also addressed specific actions NIH has taken per the legislative requirements in the 2006 reauthorization, citing the active role of the Scientific Management Review Board (SMRB) in making recommendations about NIH structure and management, including the creation of NCATS, as well as the creation of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) and its role in portfolio review and management of the NIH Common Fund and the NIH Council of Councils.