September 1, 2017

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, National Institutes of Health
31 Center Drive, Room 7A03
Bethesda, MD 20892-2520

Dear Dr. Fauci:

The Infectious Diseases Society of America (IDSA), the HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS) greatly appreciates your longstanding leadership and commitment to fostering future generations of infectious diseases (ID) physician-scientists. We have offered preliminary comments on the Next Generation Researchers Initiative (NGRI), and we appreciate the opportunity to provide additional feedback and implementation considerations to the National Institute of Allergy and Infectious Diseases (NIAID). We hope our comments will be useful in your endeavors and we would greatly appreciate the opportunity for continued dialogue with NIAID on this important issue.

Flat funding levels, sequestration, and inflation contributed to an overall 22% decline in funding levels for U.S. biomedical research between 2003 and 2015. The average age of first-time R01 funded investigators with PhDs is 42 years, even after several years of policies intended to increase the numbers of new and early stage investigators (ESIs). Likewise, the age for first-time R01-funded MDs and MD-PhDs has continued to increase. The resulting hypercompetitive research environment has had a disproportionate impact on early- and mid-career investigators, who struggle to compete for grants against researchers with a better knowledge of the system, more academic and administrative resources, and stronger publication records. Therefore, it is critical to find new ways to support early- and mid-career researchers to facilitate and stabilize the career trajectory of scientists and ensure that progress in lifesaving biomedical research remains unimpeded.

Institute-Specific Approaches to NGRI Implementation

The NGRI will place greater emphasis on special awards with the aim of supporting all ESI applications that score in the top 25th percentile. NIAID's commitment to promoting the transition from fellowship to productive research and academic careers, and its development of specialized initiatives designed to attract and retain physician-scientists, makes it well-positioned to implement the NGRI's mandate.

At NIAID specifically, early career investigators already benefit from a higher investigator-initiated R01 payline that is generally about 4 percentile points higher than the broader R01 payline. NIAID also uses selective pay and R56-Bridge Awards to ensure that promising investigators whose applications score beyond the payline receive funding.

There are also a number of Institute programs and initiatives designed to attract and retain physician-scientists that are currently under development. We applaud the NIAID for participating in the Stimulating Access to Research in Residency (StARR) R38 program but are concerned that NIAID will only be participating in the initial year of the program and not adding awardees in subsequent years like

NCI and NHLBI are planning to do. In recent years it has become increasingly difficult to support residents and subspecialty fellows for biomedical research training, which is necessary to provide the initial experiences needed to stimulate interest in the physician scientist career pathway and to develop physician scientists. According to a recent American Physician Scientists Association survey, it is often unclear which programs have opportunities for research in residency due to the structure of the match system. Setting up a program of this nature would take steps to overcome that gap. We urge NIAID to fully participate in this program.

Another possibility to promote stability for early career investigators that NIAID may wish to consider is linking the K and the R track. Similar to the NIH Pathway to Independence Award (K99/R00) for early career PhD and MD researchers, and in keeping with the Physician-Scientist (PS) Workforce Working Group recommendation, NIAID is working to develop a "Pathway to Independence" K99/R00 program for eligible physician scientists to increase the number of PS conducting biomedical research. Another potential initiative in this vein is NIAID's pending K-to-R03 competition, modeled after a similar program at the National Institute of Diabetes, Digestive, and Kidney Diseases. This program would allow existing NIAID K01, K08 and K23 awardees to apply for Small Grant (R03) research support at some point during the last two years of their K award. The impact of the program is expected to substantially increase NIAID K awardees transitioning to research independence.

Our societies support NIH's broader efforts to create a central inventory of early- and mid-career investigators in fundable ranges to help ensure the NGRI is effectively implemented across its ICs. For ESI grants that score on the cusp of the 25th percentile but ultimately are not chosen for payline or select pay funding, ICs may consider developing a formal mechanism to shift promising awards to complementary entities. For example, if a researcher working on antibiotic resistance is transitioning from K to R but does not quite hit the funding line, perhaps their application could be passed on to the NIAID-funded Antibacterial Resistance Leadership Group (ARLG) for consideration.

At a 2017 workshop attended by NIAID's T32 Program Directors, grantees discussed opportunities to strengthen the NRSA T32 research training programs. In response, NIAID is developing an R25 research education program to support various educational activities that complement and/or enhance the training experience. Applicable activities focus on research experiences, structured research mentoring activities, and courses for skills development. Continuing to engage with these participants as the NGRI is implemented will be critical to ensuring that ESIs have access to the tools and training necessary for long-term career success.

Dr. Collins has noted that "every dollar that NIH invests in research returns more than $2 in that first year into the local economy," and many studies put the return on investment in basic scientific research at 8-to-1 when considered over the long term. Working to revitalize university-government-industry partnerships as part of the NGRI would help ensure the future success of the biomedical research workforce by promoting innovation and simultaneously strengthening the economy. The NIH Fogarty International Center's Global Health Program for Fellows and Scholars provides a model for using university consortia to provide collaborative, mentored research training opportunities in low- and middle-income areas. Likewise, NIAID could build new university partnerships and leverage existing relationships to increase support and create new programs for early career researchers in previously underserved areas.

Additional Considerations and Challenges

Successful implementation of the NGRI includes assuring stable trajectories for mid-career researchers, incorporating mentorship into career development, monitoring and tracking the Initiative's outcomes and effects, incorporating feedback from multiple stakeholders, evaluating different research outcome metrics, and considering the opportunity costs of various funding strategies and decisions. NIAID should also

consider the following questions to help develop a widespread network of resources and support for early- and mid-career researchers:

- How will NIAID strike a thoughtful and empirical balance between funding merit-based research while expanding support to ESIs and mid-career investigators? Will the funding score for established researchers' grant applications be truncated (e.g., top 20th percentile vs. top 25th)?

- How can NGRI initiatives best accommodate the changing landscape of collaborative research? The system is currently set up to support individual achievement, but new researchers entering the system are often working in teams.

- If, in the future, it becomes necessary to implement some version of a funding or "points" cap for researchers to ensure sufficient resources for the NGRI, NIAID should consider ways to incentivize senior investigators to apply for grants as co-PIs with junior colleagues. We recommend that any scoring system implemented to help determine NIAID research funding be weighted such that collaborative multi-PI R01s and multi-project P and U grants are not penalized unfairly. At a time when NIH ICs are endorsing increased support for and team science, overweighting of collaborative grants would discourage PIs from contributing to collaborative efforts.

We recognize that addressing the funding challenges faced by early- and mid-career researchers will require a collaborative effort by stakeholders and other federal agencies. We stand ready to aid NIAID as it refocuses efforts on early- and mid-career investigator support, and look forward to working together to ensure the sustainable support of a diverse biomedical research infrastructure that facilitates new advances in patient care.

Sincerely,

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Chair, HIVMA Board of Directors