American Thoracic Society

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April 1, 2020

Francis Collins, MD, PhD.
Director
National Institutes of Health
31 Center Drive
Bethesda, MD
RE: NOT-OD-20-064

Dear Dr. Collins:

On behalf of the American Thoracic Society (ATS), thank you for the opportunity to provide comments on the draft NIH Strategic Plan, FY2021 – 2025. The American Thoracic Society (ATS) is a 16,000 member scientific multi-disciplinary organization dedicated to the prevention, treatment, and cure of pulmonary, critical care and sleep related illnesses through research, education, and patient advocacy. We believe the draft plan thoughtfully articulates appropriate cross-cutting themes and objectives that effectively guide the NIH's efforts over the next five years. We have the following comments:

Emerging Trans-NIH Needs:
General Comments
The ATS notes with interest and concerns OSTP's consideration of policy that would require immediate public posting of all research publications produced in whole or in part by federal research grants. While this mandate would be placed on the individual grant recipients, the policy change would have an unprecedent impact on peer-reviewed journals. Under an immediate access policy, many journals would be forced to switch from a subscription-based model to an author pays model. The ATS has done an initial estimate of how switching to an author pays model would impact publication costs to the author and is projecting significant increases in author costs, as much as $6,000.00 per manuscript, a $4,000.00 increase over the current typical author costs. In discussions with sister academic organizations, they are projecting similar author cost increases should a policy of immediate access be adopted. This would place significant financial strains on authors.

The increase in author publications costs would have a significant impact on NIH too. Currently, NIH and other federal research agencies allow grant funds to be used to cover publication costs. In 2016, NIH grant funding was acknowledged in over 115,000 academic manuscripts.[1]

[1]The STM Report An overview of scientific and scholarly publishing - 1968-2018: https://www.stm-assoc.org/2018_10_04_STM_Report_2018.pdf

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Assuming similar numbers of NIH funded publications an author pays mandate could lead to over $400 million annual increase in NIH grant funding used to pay for publication costs. Using nearly half a billion annually to pay for publications costs would divert NIH funds from spending on the underlying research. The total costs to the federal government would be much higher as the $400 million estimate is for NIH only and does not include the wide range of other federal agencies with intramural and extramural research programs that lead to academic manuscripts.

As the agency considers its strategic plan, we urge NIH to develop a detailed cost estimate of how implementing an immediate open access policy would effect author publications costs and further, how rising author cost might impact the availability of funds for investigator initiated research at NIH.

Emerging Infectious Disease Pandemics

The global pandemic of COVID-19 that emerged in December 2019 is straining the resources of the scientific and medical communities. Increased globalization of travel, commerce and communication have facilitated the frequent emergence and global spread of new infectious diseases over recent years. The ATS recommends that the NIH develop infrastructure to respond effectively to fast-moving diseases by providing accelerated funding mechanisms for short and long-term research projects in areas of clear translational potential including virulence and epidemiology, vaccine and other therapies development, diagnostic tests and training for healthcare workers and researchers.

Scientific Transparency and Rigor

Citizens of the United States and the scientific community must be able to trust the quality of science conducted by NIH researchers. Science needs to be performed and evaluated in an appropriately rigorous peer-reviewed manner and protected from political influence in the selection of grants, interpretation of study findings and the distribution of scientific information. The ATS is concerned that there are several examples of the current Administration delaying or withhold key scientific information out of political considerations. The ATS strongly urges the NIH to continue to protect and preserve the integrity and transparency of the NIH peer-review process.

Addressing Health Disparities in Innovative Therapies

The negative impact of disproportionality, based on sex, race, age, etc., in the efficacy of existing therapeutics and interventions has recently become more widely appreciated. The ATS commends the NIH for its initiatives to address health. Additionally, the ATS strongly encourages all components of the Department of Health and Human Services to ensure that emerging and future therapies address the potential for, and actively reduce, disparities in their implementation across demographic groups.

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Future Opportunities

Understanding the Ontogeny of Health and Disease

Congenital origins are evident risk factors for many pulmonary, critical care and sleep disorders. There is a growing appreciation that in utero, neonatal and childhood exposures and growth delays, in the absence of clear congenital risks, may also be common determinants for both acute health and the ontogeny of health throughout the lifespan. Unfortunately, the relationship between these early developmental events, and longer-term disease burden, have not been thoroughly defined. Furthermore, with rare exception, research on the impact of childhood exposures and respiratory, critical care and sleep diseases has been more limited than in their adult counterparts. The ATS recommends expanded investment in multi-disciplinary studies to understand the burden and mechanisms associated with the acute, chronic and persistent health impacts of developmental and childhood illnesses, with a goal of identifying interventions that will improve health across the lifespan.

Intergenerational Transmission of Health

Environmental exposures, behavior (diet, exercise, mental health), and genetics all play a role in health effects across the lifespan. Researchers and clinicians are increasingly appreciating the effect of maternal environmental exposures, behaviors and genetics on health effects in the next generation. Evidence suggests that climate change, air and water pollution, the human microbiome, obesity, anxiety and depression, drug abuse, and other factors contribute to epigenetic changes that may be transmitted from mother to child. The ATS recommends that the NIH prioritize research funding to focus on basic, clinical and translational study of intergenerational transmission of health and efforts to prevent detrimental health effects in future generations.

Address the Rising Burden of Respiratory Diseases – the Fourth Leading Cause of Death in the U.S.

Chronic lower respiratory diseases are the fourth leading cause of death in the U.S. Major pulmonary diseases such as COPD are still without disease-altering treatments and cures and because they are age-related, their impact and burden on overall health in U.S. will increase in the future. The COPD National Action Plan, released in 2017, provides a roadmap for responding to this disease through increased basic, clinical and translational research and public health efforts. We urge the NIH to provide funding to fully implement the research goal of the COPD National Action Plan. Additionally, the ATS recommends expanding efforts to promote profound understanding of the pathobiology of respiratory diseases, critical illnesses, and sleep disorders. These efforts are essential to the development of diagnostic tools, prevention strategies, and novel therapeutics to address this large and growing public health burden.

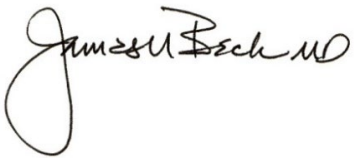
Sleep Health and Circadian Rhythm
Alterations in circadian clock and sleeping patterns are well recognized as a cause of metabolic changes, aging, neurological, respiratory and other diseases or vice versa. However, there is a lack of information on how circadian genes are involved in or are regulated by infection, dietary changes or other environmental stimuli and how this may change the outcome of all diseases. The ATS recommends that the NIH expand dedicated efforts on sleep and circadian rhythm and how these processes affect development of disease and overall health.

We have the following comments on the draft plan's objectives:

Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity
Further develop, diversify, and sustain a scientific workforce capable of carrying out the goals and objectives of the NIH Strategic Plan
A sustainable, highly skilled workforce is integral to accomplishing the goals of the NIH Strategic Plan and of improving care for all. This includes prioritizing mechanisms to develop and retain junior investigators as well as sustain established investigators. Inclusion of and equity for clinical and basic scientists, particularly women and underrepresented groups in the workforce is essential to promoting research in respiratory diseases, critical illness, and sleep disorders that is relevant to all. A focus on Team Science will encourage collaboration between basic scientists and clinicians and promote sustainability and synergy of effort.

Cross-Cutting Theme: Optimizing Data Science and the Development of Technologies and Tools and Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity
The ATS recommends that the NIH develop research sharing data applications and enable analytics on the cloud across NIH institutes to train the new generation of scientists and clinicians and enable precision medicine initiatives to benefit disease-specific research.
The ATS appreciates the opportunity to comment on the NIH Draft Strategic Plan.

Sincerely,



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