July 2022

Research News Quarterly

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In this Issue

Letter from the Editor

Our feature this month is an interview with Marishka Brown, Ph.D, Director of NIH/NHLBI's Center on Sleep Disorders Research (NCSDR). In the interview, Dr. Brown describes the strategic priorities of NCSDR's sleep portfolio and the ways in which she and her colleagues coordinate NIH's sleep-related research across other federal agencies. She also outlines the ways in which she has been able, through the pandemic, to target support for early-stage sleep investigators. She lets us know how she was able to gather ideas for the relatively recently released National Institutes of Health Sleep Research Plan.

Other articles this month include Mallar Bhattacharya's excellent summary of what we know about the new federal agency, the Advanced Research Projects Agency for Health (ARPA-H). The article is especially important since the formal establishment of this agency was announced on May 25th. Also, Jennifer Ingram and Jennifer Trevor provide a complete and up-to-date compilation of information about President Biden's appointments of those with critical roles in advising him, and others in the Administration, on matters related to science, health and climate change policy, medical and scientific research priorities, and drug and environmental regulatory policies. Nizar Jarjour, Amali Samarasinghe, and Hasina Reed have provided an important essay cataloguing the major negative impacts of the COVID-19 pandemic on clinical and laboratory-based research and on Pulmonary and Critical Care Medicine as a specialty. The authors also see a silver lining: greater societal respect for physicians and scientists and a dramatic increase in medical school applications. Hasina Reed also has contributed an article about the Harold Amos Medical Faculty Development Program, which provides funding and training to support young investigators pursuing careers in pulmonary and critical care medicine with a focus on increasing the numbers of faculty members in our specialty from diverse backgrounds. Dr. Reed herself is a former fellow in this important program. Of note is that all the authors mentioned in this paragraph are current (or recent past) members of the ATS's Research Advocacy Committee.

We round out the Quarterly with a Legislative Update from our Washington Office by Valerie A. Adelson, MHA, BSN, RN, Associate Director of Government Relations for the ATS.

Sincerely,

James K. Brown MD
Chair, Research Advocacy Committee

Research News Feature

Interview with MARISHKA BROWN, Ph.D, Director, NIH/NHLBI Center on Sleep Disorders Research (NCSDR)

1. What are the research priorities for NIH specifically related to sleep-disordered breathing?

Through the Sleep Disorders Research Advisory Board and by soliciting public input, the NIH identifies the priorities that researchers and the public consider to be the most important in the sleep space. The NCSDR has identified five strategic priorities as part of its sleep research portfolio:

- Elucidate the sleep and circadian mechanisms underlying health and disease
- Improve the treatment of sleep and circadian disorders and reduce risks associated with sleep deficiency
- Identify the opportunities to accelerate the clinical implementation of sleep and circadian research especially in areas where improvements will protect public health
- Advance the scientific understanding of sleep and circadian contributions to health disparities
- Foster the development of a strong and diverse workforce for sleep and circadian research

Within these goals are opportunities of critical importance for better understanding how sleep and sleep disorders impact overall health. For example, we could advance sleep health by identifying biomarkers that permit improved detection and monitoring of conditions such as sleep apnea or other sleep disorders, as well as acute sleep deficiency. Rather than your doctor asking if you are getting enough sleep, imagine if your doctor could tell you the answer based on a lab test. Emerging data indicate that the impact of COVID-19 on sleep may be substantial. Identifying the priorities in basic and clinical research related to the impact of acute COVID-19, as well as the impact of Long-Haul COVID and other post-acute sequelae of SARS-CoV-2 infection on sleep health, is critical.

2. How do you coordinate research on sleep and specifically sleep-disordered breathing across disease states and across NIH institutes?

Sleep disorders, including sleep-disordered breathing issues, require a multidisciplinary approach to identify specific risks to health, develop diagnostic tools, and improve therapies. To coordinate NIH's sleep-related research efforts and interests, NCSDR meets monthly with the trans-NIH Sleep Research Coordinating Committee that is composed of program representatives across the NIH from multiple institutes, centers, and offices. In addition, NCSDR serves as the coordinating entity for other federal agencies with interests in sleep science, including the Centers for Disease Control and Prevention, the Department of Defense, the Department of Transportation, and many others. The Federal Interagency Fatigue Management Work Group meets twice per year. NCSDR continues to build new relationships with other entities, as well.

I also chair the working group responsible for creating and implementing national sleep health objectives as part of the U.S. Department of Health and Human Services Healthy People 2030 initiative.

As more sleep findings emerge, they can be added to the National Sleep Research Resource (NSRR). There are plans for the NSRR data to be hosted in the future by NHLBI's BioData Catalyst, a cloud-based data platform that gives qualifying researchers access to tools for analyzing large datasets, sharing results among users in real time, and collaborating in a virtual workspace to speed advances in sleep health research.

3. How does the NCSDR plan to continue to support and recruit scientists, particularly physician scientists with joint expertise in sleep and respiratory physiology?

NHLBI continues to prioritize investigator-initiated research and welcomes applications from academic and physician scientists with expertise in sleep and/or respiratory physiology. Moreover,

we continue to provide targeted support to early-stage investigators (ESIs), especially during this extraordinarily difficult year in which research was heavily impacted by the COVID-19 pandemic. Following the lead of the NIH Office of Extramural Research, we extended maximum supports to junior physician-scientists whose research or labs were impacted by pandemic lockdowns and other restrictions. These supports included extending certain deadlines, holding virtual meetings and trainings, and forgiving failures to meet certain clinical trial milestones when applicable. In FY20, NHLBI was able to fund R01 applications up to the 16th percentile, and the pay line for ESI applications was set at the 26th percentile. For FY22, the Institute aims to maintain similar pay lines. In these most challenging years, we truly appreciate the ATS's partnership as we maintain our commitment to supporting the next generation of physician scientists.

4. How can ATS and other professional societies interested in sleep-disordered breathing partner with NCSDR? How can they provide input on the priorities of NCSDR?

We value the support and input of the ATS and other professional societies for NHLBI's sleep research portfolio. NCSDR issued a request for information on the proposed NIH Sleep Disorders Research Plan Critical Opportunities and Strategic Goals, an update of the NIH Sleep Disorders Research plan that was last published in 2011. The information collected through this RFI and the NCSDR IdeaScale Campaign was used to produce the relatively recently released the National Institutes of Health Sleep Research Plan: Advancing the Science of Sleep & Circadian Biology Research. We look forward to continued dialogue with experts in the sleep and respiratory fields as we refine and implement our sleep research priorities. ●

ARPA-H

Transforming Biomedical Research in the United States

Mallar Bhattacharya, MD

In remarks to a joint session of Congress on April 28, 2021[1], President Biden introduced his vision for a new federal agency, the Advanced Research Projects Agency for Health (ARPA-H). The broad vision of ARPA-H is to accelerate discovery of solutions for the most important health problems facing Americans. Mr. Biden invoked the concept of the now well-established Defense Advanced Research Projects Agency (DARPA), which was created in the 1950s to develop transformative engineering technologies for national security. Similarly, ARPA-H "would have a singular purpose: to develop breakthroughs to prevent, detect, and treat diseases". Mr. Biden's FY2022 budget proposed $6.5 billion funding over three years for ARPA-H. Following the President's announcement, former NIH Director Francis Collins and former Director of the White House Office of Science and Technology Policy Eric Lander with others published an article in Science detailing the vision for ARPA-H[2]. As stated in the article, ARPA-H's mission statement would be "To make pivotal investments in breakthrough technologies and broadly applicable platforms, capabilities, resources, and solutions that have the potential to transform important areas of medicine and health for the benefit of all patients and that cannot readily be accomplished through traditional research or commercial activity."

15 listening sessions held by NIH and the White House Office of Science and Technology Policy between July and August of 2021 provided perspective on the vision for ARPA-H. A summary report[3] outlined how ARPA-H will differ from the existing federal research infrastructure represented by NIH and BARDA. One important goal for ARPA-H is to fill a perceived research gap between industry and academia. In Eric Lander's words, "NIH support for science traditionally favors incremental, hypothesis-driven research, while business plans require an expected return on investment in a reasonable time frame that is sufficient to attract investors…bold ideas involve creating platforms, capabilities, and resources that could be applicable across many diseases. Whereas most NIH proposals are 'curiosity-driven', these ideas are largely 'use-driven' research — that is, research directed at solving a practical problem."[4]

Several principles put forth during the listening sessions helped to clarify how this vision will be realized. First, there will be a focus on harnessing technology, including nanotechnology, AI, and digital solutions, to advance health across a broad spectrum, from molecular therapeutics to medical informatics. Second, ARPA-H will foster high-risk, high-reward projects that are not supported by existing programs at NIH or in industry, emphasizing a rapid translation from concept to commercialization. Embedded within this project-based approach is an emphasis on supporting goal-oriented teams rather than the single investigator-initiated model supported by the NIH. Third, ARPA-H will foster interdisciplinary collaboration to harness a broad range of expertise and will also prioritize equity and diversity at every stage of project development and personnel recruitment.

How will the project-focused structure of ARPA-H be organized?

ARPA-H projects will be led by Program Managers (PM) who will report to the ARPA-H Director. In his comments during the first listening session, Dr. Collins expressed a vision for both the Director and PMs as individuals with private sector experience and entrepreneurial spirit. PMs will be chosen, from both industry and academia, based on the novelty and tractability of their ideas around specific programmatic priorities. Each program will be held to specific deliverables, and PMs will be engaged for 3 years, potentially renewable up to a 5-year term, with a mandate of engaging investigators and collaborators from academia, industry, and nonprofits to drive the research forward toward clear milestones.

What will be the disease focus of ARPA-H?

Discussions with scientific society-based stakeholders at the July 22nd, 2021, listening session revealed the broad-based focus of ARPA-H across a wide spectrum of health domains affecting Americans. The emphasis per Dr. Collins will be the potential for use-based applications—that is, projects with a high likelihood of breaking pre-existing barriers to providing concrete solutions for existing challenges.

What is the current state of the establishment of ARPA-H?

On March 15th, President Biden signed into law the appropriation of $1 billion to HHS for the creation of ARPA-H, as part of the FY 2022 $1.5 trillion omnibus funding bill; the funding is to be spent within 3 years and is considered start-up funding to launch ARPA-H.[5] On May 25th, Health and Human Services Secretary Xavier Becerra announced the formal establishment of ARPA-H as an independent entity within the National Institutes of Health. He also announced the appointment of Adam H. Russell, D. Phil., as acting deputy director. Most recently, Dr. Russell has been the Chief Scientist at the University of Maryland's Applied Research Laboratory for Intelligence and Security. He spent more than a decade prior to holding that position as a Program Manager, first at the Intelligence Advanced Research Projects Activity and then at DARPA. ●

1. https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/29/remarks-by-president-biden-in-address-to-a-joint-session-of-congress/
2. Collins, F. S., Schwetz, T. A., Tabak, L. A. & Lander, E. S. ARPA-H: Accelerating biomedical breakthroughs. Science 373, 165-167, doi:10.1126/science.abj8547 (2021).
3. https://www.nibib.nih.gov/arpa-h-listening-session.
4. https://www.whitehouse.gov/wp-content/uploads/2021/06/ARPA-H-Concept-Paper.pdf.
5. https://www.science.org/content/article/u-s-just-created-big-new-biomedical-research-agency-questions-remain

Biden Administration Scientific and Health Policy Cabinet

Jennifer L. Ingram, PhD ATSF, and Jennifer Trevor, MD

With the inauguration of Joseph Biden as the 46th President of the United States in January 2021, a new Administration took office. President Biden immediately nominated new Cabinet members and other leaders within the administration that are serving in critical roles to advise the President and the Administration on matters involving science, health and climate change policy; medical, environmental, and scientific research priorities; and drug and environment regulatory policies. In this article, we provide a summary of the heads of key offices that are advising the President on issues of high interest to members of the ATS.

Secretary of the Department of Health and Human Services (DHHS)
Xavier Becerra, JD

After completing his law degree at Stanford Law School, Mr. Becerra went on to serve over twenty years in Congress as a member of the U.S House of Representatives from California. He served on the Committee on Ways and Means, as the Ranking Member of the Ways and Means Subcommittee on Social Security and Subcommittee on Health and was an original co-sponsor of the Patient Protection and Affordable Care Act (ACA). He then served as Attorney General for the State of California from January 2017 until March 2021, where he litigated policies on issues of immigration and the environment and led a 3-year court fight to save the ACA. He was appointed the first Latino to head HHS by the Biden administration and approved by the Senate in March 2021.

Director, Centers for Disease Control (CDC)
Rochelle Walensky, MD, MPH

Dr. Walensky received her MD from Washington University in St. Louis, completed a residency in Internal medicine at John Hopkins, and a fellowship in Infectious Disease at Massachusetts General Hospital/Brigham and Women's Hospital along with an MPH from the Harvard T.H. Chan School of Public Health. She remained on faculty at Harvard Medical School where she rose to the rank of Professor and Chief of Infectious Diseases. Her career has focused on cost effective strategies for care of human immunodeficiency virus (HIV) patients in the U.S. and resource limited settings. She has served on the DHHS Panel for Antiretroviral Guidelines for Adults and Adolescents and chaired the National Institutes of Health (NIH) Office of Acquired Immunodeficiency Syndrome (AIDS) Research Advisory Council.

Surgeon General
Vivek Murthy, MD, MBA

Dr. Murthy completed his MD at Yale School of Medicine and MBA at Yale School of Management in 2003 and then went on to complete his Internal Medicine residency at Brigham and Women's Hospital before briefly serving on the Harvard Medical School faculty. In 2011, President Obama appointed him to the Presidential Advisory Council on Prevention, Health Promotion, and Integrative and Public Health within the Department of Health and Human Services. Then, in December 2014, President Obama appointed him to serve as U.S. Surgeon General, a post he held until April 2017. During his term, he focused on a range of issues including physical activity, the opioid crisis, e-cigarette use, Zika and Ebola. In addition to these accomplishments, he founded multiple non-profit organizations including Doctors for America, an advocacy organization seeking equitable and affordable healthcare for all Americans.

Commissioner, Food and Drug Administration (FDA)
Robert Califf, MD, MACC

Dr. Califf served as Commissioner of Food and Drugs Under President Obama from February 2016 to January 2017. He is a member of the National Academy of Medicine and has served on several FDA panels including the Cardiorenal Advisory Panel and FDA Science Boards Subcommittee on Science and Technology. Prior to joining the FDA, he was faculty at Duke where he served as vice chancellor for clinical and translational research, director of the Duke Translational Medicine Institute, founding director of the Duke Clinical Research Institute, and lead initiatives such as Clinical Trials Transformation Initiative (CTTI). He is a cardiologist by training, completing his fellowship training in cardiology at Duke.

Director, National Institutes of Health (NIH)

Dr. Francis Collins, MD, PhD, long-time Director of the NIH, recently resigned from this position. His permanent replacement has not been announced at this time. Dr. Lawrence A. Tabak, DDS, PhD is currently Acting Director of the NIH.

Lawrence A. Tabak, DDS, PhD

Prior to joining the NIH in 2000 where he was named director of the National Institute of Dental and Craniofacial Research and the deputy ethics counselor, Dr. Tabak had a long and distinguished career at the University of Rochester where he served as the associate dean for research and the director of the Center for Oral Biology. Dr. Tabak received his DDS from Columbia University and his PhD in endodontics from University of Buffalo. His research interests include the structure, biosynthesis, and function of glycoproteins. His appointment is notable as he is believed to be the first dentist to lead the NIH.

Director, Agency for Healthcare Research and Quality (AHRQ)
Robert Otto Valdez, PhD, MHSA

Dr. Valdez received a master's degree in Health Policy and Administration followed by his PhD in Public Policy Studies from Pardee RAND Graduate School focusing on healthcare financing and quality. Under the Clinton administration, he served as Special Senior advisor to the Whitehouse on healthcare reform, the Deputy Secretary for Health with the DHHS, as well as the Director of the Interagency Health Policy. Immediately prior to assuming his current role he was the Robert Wood Johnson Foundation Professor Emeritus of Family and Community Medicine and Economics at the University of New Mexico.

Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)
Patrick Breysse, PhD, MHS

Dr. Breysse received his PhD from Johns Hopkins in Environmental Health Engineering in 1985 and then completed his post-doctoral training at the British Institute for Occupational Medicine in Edinburgh, Scotland. Prior to his current appointment, he was a Professor at Johns Hopkins where he served as Associate Chair for Educational Programs within the Department of Environmental Health Sciences, Program Director for the Industrial Hygiene Training Program, and co-director of the Johns Hopkins Center for Childhood Asthma in the Urban Environment. He first joined the CDC as Director of the NCEH/ATSDR in 2014 where he has been investigating the relationship between the environment and health.

Administrator, Environmental Protection Agency (EPA)
Michael Regan, MPA

After completing his master's in public administration from George Washington University, Mr. Regan began his career with the EPA in 1998 as an environmental regulator before joining the Environmental Defense Fund where he held the position of Associate Vice President of U.S. Climate and Energy. Then, in 2017, he was selected to serve as the secretary of the North Carolina Department of Environmental Quality. During his tenure he secured an agreement for the largest coal ash clean-up in U.S. history with Duke Energy and negotiated the clean-up of the Cape Fear River with chemical company Chemours. Additionally, he established an Environmental Justice and Equity Board in North Carolina to address issues of social inequity and the environment. He is the first African American man to hold the position of U.S. EPA Administrator.

National Climate Advisor
Gina McCarthy, MS

Ms. McCarthy was appointed to serve as the first ever National Climate Advisor to the Biden administration. She received her Master of Science in Environmental Health Engineering and Policy and Planning from Tufts University in 1981. Following many years of service at the state level working on matters of environment and health in Massachusetts and Connecticut, she joined the Environmental Protection Agency (EPA) in 2009 as Assistant Administrator for EPA's Office of Air and Radiation. From July 2013 to January 2017, she served as EPA Administrator under President Obama. After leaving her position in 2017, she joined the faculty at Harvard University's T.H. Chan School of Public Health. In 2020, she became President of the Natural Resources Defense Council (NRDC). Her priorities as the National Climate Advisor include rejoining and supporting the Paris Climate Agreement and lowering domestic greenhouse gas emissions while fostering job growth through innovation and investment in green technology.

Special Presidential Envoy for Climate
John Kerry, BA

Following a very long and distinguished career as a Senator, Presidential candidate, and most recently Secretary of State (2013-2017) under President Obama, where he helped negotiate the Paris Agreement on Climate Change, John Kerry is serving as the first ever Special Presidential Envoy for Climate. This role is a new position within the executive office of the president, focused on combating climate change with authority over White House energy and climate policy, as well as a seat on the National Security Council. John Kerry's priorities are in line with Administrator McCarthy, which are to develop a comprehensive strategy to reduce U.S. greenhouse gas emissions, with an emphasis on the automotive industry.

Office of Science and Technology Policy (OSTP)

The OSTP advises the President and other members of the Administration on issues involving science, engineering, and technology. President Biden elevated the Director of OSTP to a Cabinet-level position within the Administration.

Director, White House Office of Science and Technology Policy
Alondra Nelson, PhD

Dr. Nelson is the Harold F. Linder Professor at the Institute for Advanced Study, an independent research center in Princeton, New Jersey. Previously, she was Professor and Dean of Social Science at Columbia University. She is also Past president of the Social Science Research Council. She has written several books connecting the study of genomics, medicine, and race, including The Social Life of DNA: Race, Reparations, and Reconciliation after the Genome, Body and Soul: The Black Panther Party and the Fight against Medical Discrimination, as well as Genetics and the Unsettled Past: The Collision of DNA, Race, and History (with Keith Wailoo and Catherine Lee), and Technicolor: Race, Technology, and Everyday Life (with Thuy Linh Tu).

Co-Chairs, President's Council of Advisors on Science and Technology
Frances Arnold, PhD, MS

Dr. Arnold is the Linus Pauling Professor of Chemical Engineering, Bioengineering and Biochemistry at the California Institute of Technology. In 2018, she was awarded the Nobel Prize in Chemistry for her work on directed evolution to engineer enzymes. She is a member of the National Academy of Engineering and the Director of the California Institute of Technology Donna and Benjamin N. Rosen Bioengineering Center. Her research focuses on using directed evolution techniques to develop highly selective and efficient enzymes for improving chemical synthesis processes to make them more environmentally friendly.

Maria Zuber, PhD, MS

Dr. Zuber is the E.A. Griswold Professor of Geophysics and the Vice President for Research at Massachusetts Institute of Technology. Her research focuses on using space-based gravity, radio, and laser systems to investigate interior structures of solid objects in our solar system. She has held leadership roles associated with scientific experiments on ten NASA missions, most notably serving as Principal Investigator of the Gravity Recovery and Interior Laboratory (GRAIL) mission, the first woman to serve in that role for a NASA planetary mission. She is also the first woman to lead a science department at MIT. In 2013, President Obama appointed her to the National Science Board, and in 2018 she was reappointed by President Trump. She served as Board Chair from 2016-2018.

Chief of Staff
Marc Aidinoff, PhD

Dr. Aidinoff holds a PhD in Science, Technology and Society from the Massachusetts Institute of Technology. He is an experienced science policy expert trained in the history and sociology of science. Prior to joining OSTP, he worked in data analytics for OpenLabs USA and Civis Analytics. During the Obama Administration, Aidinoff served as the Assistant Director for Domestic and Economic Policy to then-Vice President Biden from 2013 to 2015.

COVID-19 Response Program

Chief Science Officer for the COVID-19 Response
David Kessler, MD, JD

Dr. Kessler is a pediatrician and attorney who served as FDA Commissioner under both the George H.W. Bush and Bill Clinton administrations. He also served as Dean of the School of Medicine at Yale University and Dean and Vice-Chancellor of the University of California-San Francisco Medical School. In 2008, he was awarded the Public Health Hero award by the University of California- Berkeley School of Public Health for his work in tobacco regulation. He was named by President Biden to oversee Operation Warp Speed, the program for development of vaccines against SARS-CoV2. He has written several books, including, The End of Overeating: Taking Control of the Insatiable American Appetite, a New York Times bestseller.

Coordinator for the COVID-19 Response
Ashish iha, MD, MPH

Dr. Jha is a physician and health policy researcher, currently serving as Dean of the School of Public Health and Professor of Health Services, Policy and Practice at Brown University. Formerly, he was the K.T. Li Professor of Global Health at the Harvard University T.H. Chan School of Public Health, Dean for Global Strategy and Director of the Harvard Global Health Institute. He is an expert on pandemic preparedness and response, health policy and practice. His research interests focus on improving the quality and costs of healthcare delivery and the impact of policy efforts. He was elected to the National Academy of Medicine in 2013.

Chief Medical Advisor (and head delegate to the World Health Organization)
Anthony Fauci, MD

Dr. Fauci has been director of the National Institute of Allergy and Infectious Diseases (NIAID) for nearly four decades. He is also the chief of the Laboratory of Immunoregulation, and his research focuses on investigation of host immune responses and pathogenic mechanisms of HIV infection and other immunodeficiency diseases. He has advised seven presidents on HIV/AIDS and many other domestic and global health issues. In 2008, President George W. Bush awarded Fauci the Presidential Medal of Freedom for his work on the AIDS relief program, President's Emergency Plan for AIDS Relief, PEPFAR. He served on the previous administration's White House Coronavirus Task Force beginning in January 2020.

Chair, COVID-19 Health Equity Task Force
Marcella Nunez-Smith, MD, MHS

Dr. Nunez-Smith is Associate Professor of Internal Medicine, Public Health, and Management and Associate Dean for Health Equity Research at Yale University. She is also the founding Director of the Equity Research and Innovation Center (ERIC) at Yale. Her research focuses on working towards health and healthcare equity for marginalized populations through community engagement, increasing workforce diversity and development of tools for measuring healthcare quality among patients.

The team also includes Janet Woodcock, Rochelle Walensky, Xavier Becerra, and Vivek Murthy, listed above. Andy Slavitt, MBA also served as Senior White House Pandemic Advisor until June 2021. ●

The Impact of COVID-19 Pandemic on Clinical Research

Nizar Jarjour, MD; Amali Samarasinghe, PhD; Hasina Outtz Reed, MD, PhD

I: INTRODUCTION

COVID-19 has had major repercussions on practically every aspect of our lives since December 2019. Clinical research has been no exception, with the pandemic having had a major impact on academic physicians, patients, and sponsors of clinical research, from industry to the National Institutes of Health to disease-focused foundations. Physician scientists have faced added pressures with the need to respond to increased clinical loads imposed by the rise in COVID-19 patient numbers, especially during surges across the US and the globe. As a result, researchers have found themselves behind the expected milestones with regards to publications, promotions, and funding. Physician scientists, as part of the health care workforce, have been called upon to help with the national response to the pandemic. Physicians from underrepresented minorities have confronted additional expectations to help support communities hardest hit with the pandemic, to disseminate information about appropriate precautions, and to address vaccination hesitancy.

II: IMPACT ON CLINICAL RESEARCH

Most non-COVID clinical trials were curtailed or completely halted beginning with the initial surge of the pandemic. Since then, clinical research studies have gradually resumed operation, but with several modifications including revised protocols, abbreviated schedules, and the need for PPEs, pre-visit testing for COVID-19, use of electronic means of communications, and telehealth. When health care systems were confronted with the rapidly rising demands of the pandemic, redirection of available resources became necessary. This led to a temporary pause

in non-urgent, in-person visits and a halt to non-therapeutic trials. In that environment, it was difficult to initiate clinical trials except for those related to COVID-19. Furthermore, initiated trials that were already underway faced difficulties in recruiting subjects as well as in addressing the safety concerns of subjects and staff. These challenges were especially difficult because of the evolving nature of recommendations during the early phase of the pandemic. Investigators and sponsoring agencies responded by implementing modifications to study protocols to allow greater flexibility in timing of clinical research visits, by using telephone or video visit, and by incorporating remote monitoring tools.

An additional complicating factor was that participants in research trials often were infected with the SARS-COV-2. Alternatively, they needed to be off a given study medication to receive vaccination against COVID-19 because the study medication might affect their responses to vaccines. To reduce the risk to research staff, lung function testing and airway sampling procedures were placed on hold early in the pandemic due to the concerns regarding generation of aerosols. This constraint significantly impacted data collection in many pulmonary clinical trials. The restriction eased with wide implementation of staff vaccination, with availability of rapid testing for COVID-19, and with use of PPE for aerosol generating procedures. Not surprisingly, research subjects were at times very reluctant to come into the clinical research environment for fear of exposure to COVID.

Some clinical assessments, such as cardiopulmonary exercise challenge to measure VO2 Max, were placed on hold with significant negative impact on clinical research and training of pulmonary fellows. Investigators and sponsors adapted to the constraints of the pandemic by implementing new approaches, including use of new technologies to facilitate remote conduct of clinical trials by telephone, email, docu-sign, or eConsent. Notable new communication technologies included Zoom, WebEx, and TEAMS. There were pressures and delays related to the research staff becoming infected or needing to quarantine after a high-risk exposure. Therefore, timelines had to be extended for many studies including some large clinical trials funded by NHLBI. Efforts to shift from in-person visits to remote monitoring and telemedicine visits paralleled those implemented in the clinical care arena. There were many advantages, such as less travel and improved ease of scheduling, but also some disadvantages, such as loss of in-person connections and inability to perform the traditional physical examination. Some studies were closed, with funding being shifted towards infectious disease-related studies. The same was true for some of the investigators who felt a sense of duty to shift their effort to studying COVID-19. The delays and extended timelines for research made completing research projects more difficult. Many clinical research and trials now are behind schedule. There will no doubt be a delay in bringing new drugs and devices to the market.

III: IMPACT ON LABORATORY AND RESEARCH PROCEDURES

The impact of the pandemic has not been limited to clinical research and clinical procedures. Laboratory studies also were also halted. Even as some of the work was allowed to resume, there were constraints on the number of people allowed in laboratory space at one time. With slowed research and delayed funding, there were freezes on hiring and recruitments. The requirement to use PPEs and to limit in-person meetings and discussions added to these difficulties. Many of the impromptu gatherings around the coffee machine or in the break room became distant memories. In addition, many national professional society meetings were cancelled, curtailing opportunities for research dissemination and networking. This led to fewer opportunities for spontaneous discussion of research experiments and troubleshooting or sharing of expertise. Various safety measures were implemented by institutions (e.g.: frequent cleaning/decontamination of surfaces; maintaining daily health records and temperatures). One result was that shifting efforts in the laboratory toward these activities reduced time for productive work. Prolonged closures led to staff departures. Even after the reopening of the labs, there were continued difficulties with staffing and recruitment. Clinical and laboratory research may become less attractive to potential future scientists as postdoctoral fellows experience reduced access to bench research and a significant negative impact on the development of their skills and experience.

IV: THE IMPACT ON THE PULMONARY AND CRITICAL CARE RESEARCHERS

Pulmonary and Critical Care Medicine has been one of the most impacted specialties. Caring for the critically ill and comforting those dying alone has strained provider well-being. It comes as no surprise that our specialty has had a high level of burnout. Physician scientists, who faced the same increased clinical expectations as their more clinical colleagues, had the added pressure of sustaining a research career under these difficult conditions. With decreased interest in academic research among trainees, we may have greater difficulty in the development of future investigators. Some basic and clinical researchers have shifted their focus to higher paying jobs in industry. The impact on the pipeline of physician-scientists in our field remains to be seen.

V: THE SILVER LINING

While many changes were forced upon the academic community by the pandemic, there is a clear opportunity to change the ways in which clinical research is conducted in the future. From telehealth to remote monitoring and electronic diaries, many changes in clinical research are here to stay. Among the most welcome adaptation has been the wide use of web-based meeting forums, allowing for wider exchange of research ideas. The human impact of the pandemic on academic pulmonary workforce has been

significant and will likely be palpable for years to come. Despite the many difficulties and distractions, scientists and physicians have earned societal respect because of their sacrifices and contributions. It is unclear what might be the long-term impact on the careers of physician scientists. Will they show greater resilience or more vulnerability? Will they adapt with increased creativity - or chose to give up research and switch to clinical careers? As a society, we need to harness the good will generated during the pandemic to build continued support for physician scientists, especially among our early career colleagues. There is renewed excitement about science driven by the development of vaccines in record time. In addition, more than ever, physicians are viewed as leaders in their community and protectors of the society. There has been a dramatic increase in medical school applications. Hopefully, these forces will spell continued interest in medical careers, clinical research, and support for increased research funding in the future. ●

The Harold Amos Medical Faculty Development Program

Hasina Outtz Reed, MD, PhD

The American Thoracic Society, American Lung Association, and American College of Chest Physicians are partnering with the Harold Amos Medical Faculty Development Program (AMFDP) to provide funding to support early career investigators pursuing careers in pulmonary and critical care medicine. The AMFDP is an initiative by the Robert Wood Johnson Foundation and was created in 1983 to increase the number of faculty from diverse backgrounds at senior ranks in academic medicine, nursing, and dentistry. It was named in honor of Dr. Harold Amos, the first African American to chair a department at the Harvard Medical School. This program has an impressive track record of success, with more than 75% of the scholars of this program remaining in academic medicine. In addition, graduates of this program have gone on to be leaders in the field, including multiple Department chairs, Division Chiefs, leaders of Institutes at the NIH, and members of the National Academy of Medicine. This scholarship provides awards of $420,000 over 4 years, and awardees conduct research with a senior faculty member at their institutions located at an academic medical center, dental school, or school of nursing. In addition, scholars are provided with mentors through the program's National Advisory Committee and attend an Annual Conference which consists of both research presentations and discussions centered on professional development. More information about this award and eligibility can be found at https://www.amfdp.org and questions about the program can be directed to Nina Ardery at amfdp@indiana.edu. ●

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Legislative Update

Valerie Adelson

President Biden submitted to Congress the President's Budget for fiscal year (FY) 2023, which begins on October 1. Though the budget will set the tone for the legislative scramble ahead of midterm elections in November, historically, it is never passed in full. The President's budget explains the policy priorities of the Administration for Congress to consider and then advance its own fiscal proposals. The Washington Office will closely monitor the FY 2023 appropriations process as competing budget proposals move through the House and Senate. ●

	President's Budget FY2023	FY2022 Enacted
NATIONAL INSTITUTES OF HEALTH	$49.04 billion in budget authority (includes $5 billion for the new Advanced Research Projects Agency for Health within NIH)	Increase of $4.31 billion over FY2022
NHLBI	$3.82 billion	Increase of $14 million over FY2022
NIAID	$6.27 billion	Decrease of $54 million from FY2022
NCI	$6.71 billion	Decrease of $199 million from FY2022
NINR	$199 million	Increase of $18 million over FY2022
NIMHD	$660 million	Increase of $201 million over FY2022
NIEHS	$932 million	From Labor, Health and Human Services Appropriations, a proposed increase of $90 million over FY2022 and $83 million from the Interior-Environmental Appropriations, level -funding from FY2022
ARPA-H	$5 billion	Increase of $4 billion over FY2022
CENTERS FOR DISEASE CONTROL AND PREVENTION	$10.675 billion	Increase of $2.27 billion over FY2022
Chronic Disease Prevention and Health Promotion	$1.61 billion	Increase of $274 million above FY2022
Chronic Disease Education and Awareness	$1.47 million	Reduction of $1.5 million from FY2022
Asthma	$30 million	Decrease of $500,000 from FY2022
NIOSH	$345 million	Decrease of $7 million from FY2022
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Infection and Tuberculosis	$1.5 billion	Increase of $126 million
Tuberculosis	$135 million	Level funded with FY2022
Environmental Health	$402 million	Increase of $174 million above FY2022
Climate and Health Program	$110 million	Increase of $100 million above FY2022
ENVIRONMENTAL PROTECTION AGENCY	$11.881 billion	Increase of $2.644 billion over FY2022
DEPARTMENTOF VETERANS AFFAIRS/ Medical and Prosthetic Research	$916 million	Increase of $34 million (3.9%) over FY2022
DEPARTMENT OF STATE/Global Fund to Fight AIDS, Tuberculosis and Malaria	$2 billion	Increase of $300 million over FY2022