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Letter from the Editor

Our feature article this month, by Michael Falvo, PhD, and colleagues, provides an overview of efforts both within the ATS and through the VA, to advance the respiratory health of veterans through several programs including the New Jersey War-Related Illness and Injury Study Center as a VA Center of Excellence and the Post Deployment Cardiopulmonary Evaluation Network (PDCEN).

Next is an update on rare disease research by ATS PAR member Michele Mannion focusing on NCATS's Rare Disease Clinical Network, followed by a timely perspective by Laertis Ikonomou, PhD, and Daniel J. Weiss, MD, PhD, on the marketing of unproven cell-based treatments to patients with respiratory diseases. This month's *Quarterly* also includes an update from Past ATS President Thomas Ferkol, MD, on the Genetic Disorders of Mucociliary Clearance Consortium.

Moving to NIH, Research Advocacy Committee member Jennifer Ingram, PhD, provides an overview on NIH's new sexual harassment policy, followed by the announcement of PCORI's new Executive Director. The NIH Office of Disease Prevention's recent feature of tobacco-related regulatory and prevention initiatives over the past year is the focus of our next article.

The March *Quarterly* features ATS President James Beck's recent message to the ATS membership on the evolvement of the ATS Foundation, including the Foundation's 2019-2020 awardees. We round out the *Quarterly* with the latest report from our Washington office on the President's 2021 budget proposals on federal health research funding.

Sincerely,

Veena Antony, MD
Editor
Chair, Research Advocacy Committee

VETERANS HEALTH

Advancing the Post Deployment Respiratory Health of Veterans

By **Anays Sotolongo MD, Michael Falvo PhD, Mehrdad Arjomandi MD, Stella Hines MD, Silpa Krefft MD,** and **John Osterholzer, MD**

Since 2001, over 2.7 million United States military personnel have been deployed to Southwest Asia to support Overseas Contingency Operations. These deployment regions are characterized by high-levels of fine particulate matter (PM) air pollution from multiple sources[1], often exceeding military and occupational guidelines, which has contributed to concerns regarding respiratory and non-respiratory health effects.

ATS convened a workshop on this topic at the 2018 conference and an Official ATS Workshop Report was recently published in the Annals of the ATS,[2] "Respiratory Health after Military Service in Southwest Asia and Afghanistan." This Workshop Report summarized key studies, described emerging research and highlighted critical knowledge gaps of interest to the ATS research community including, but not limited to:

- Lack of long-term follow-up among deployers with respiratory symptoms and exposure concerns with or without respiratory disease.
- Consistency in characterization of specific histologic abnormalities, such as constrictive bronchiolitis.
- Incidence of respiratory health conditions or cardiopulmonary function over time among veterans and active military personnel.
- Better characterization of PM exposure during deployment.

This workshop was motivated by a series of studies funded by the Department of Veterans Affairs (VA) and the Department of Defense and involving ATS members. As the largest integrated health care system in the country, VA medical records have been utilized to investigate the prevalence of chronic lung disease among veterans deployed to Southwest Asia. Pugh and colleagues[3] explored medical record data over fiscal years 2003 – 2011 and found an increasing prevalence of medical encounters for asthma, COPD and interstitial lung disease. After adjustment for covariates, the increase in encounters for asthma and COPD remained significant. In support of these findings, the Department of Defense's prospective Millennium Cohort Study found that combat deployers had an approximately 30 percent increased risk of developing new-onset asthma in comparison to non-deployers, but deployers without combat did not have an elevated risk[4]. The latter study highlights the unique nature of military service and additional factors that may augment risk to airborne hazards exposure.

The VA's Office of Research and Development continues to be proactive in studying deployment-related lung health. The multi-site study, Service and Health Among Deployed Veterans (SHADE), is currently recruiting veterans at six VA Medical Centers across the country and is designed to better characterize potential relationships between respiratory symptoms, clinical respiratory diagnoses, and pulmonary function with prior particulate matter exposure. This novel and powerful approach will allow investigators the ability to leverage archival satellite data from NASA to objectively quantify particulate matter exposure on an individual basis.

The VA has also sought to make more effective use of the national Airborne Hazards and Open Burn Pit Registry, a comprehensive questionnaire in which veterans self-report their deployment-related exposures and any development of symptoms or clinical diagnoses thereafter, including those pertaining to the lungs. One of the first studies using this data observed a moderate, independent association between self-reported blast exposure and current cardiopulmonary symptoms[5]. This study highlights the importance of considering non-inhalational exposures during military deployment when evaluating respiratory health.

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Quarterly Feature: Veterans Health *(Continued from page 2)*

In May 2019, Congress and the President formally designated (Public Law 115-929) the Airborne Hazards and Burn Pits Center of Excellence (AHBPCE) at the New Jersey War Related Illness and Injury Study Center as a VA Center of Excellence. The Center conducts clinical and translational research related to airborne hazards and burn pits focusing on a range of health outcomes including unexplained shortness of breath, dyspnea, among other related respiratory concerns. In addition, the AHBPCE has established a network of VA pulmonologists, referred to as the Post Deployment Cardiopulmonary Evaluation Network (PDCEN) to conduct clinical evaluations enabling the ABHBPCE to expand the clinical study of identified Veterans. The PDCEN is currently led by ATS members located at the following sites:

- AHBPCE at VA New Jersey Health Care System – East Orange, NJ
  - Director, Anays Sotolongo, MD
- VA Ann Arbor Health Care System – Ann Arbor, MI
  - Site Director, John Osterholzer, MD
- Baltimore VA Medical Center – Baltimore, MD
  - Site Director, Stella Hines, MD
- Rocky Mountain Regional VA Medical Center – Aurora, CO
  - Site Director, Silpa Krefft, MD
- San Francisco VA Health Care System
  - Site Director, Mehrdad Arjomandi, MD

An early goal of the PDCEN will be to use the Airborne Hazards and Open Burn Pit Registry to identify veterans who may have a deployment-related lung condition and to perform comprehensive multi-disciplinary evaluations in hopes of better characterizing these conditions while also developing guidelines for clinicians who may encounter these individuals in their clinical practice. ■

RARE DISEASES

Rare Diseases Clinical Research Network: Collaborating to Accelerate Pulmonary Research

By **Michele Manion, PAR member, ATS Research Advocacy Committee, & vice president, PCD Foundation**

The NIH National Center for Advancing Translational Science (NCATS) recently announced grant recipients for their fourth round of funding for the Rare Diseases Clinical Research Network (RDCRN). The RDCRN is a program of the Office of Rare Diseases Research (ORDR) at NCATS. Among the awardees for these five-year grants are two research consortia, the Genetic Disorders of Mucociliary Clearance Consortium (GDMCC—see description in this issue of the Quarterly) and the Rare Lung Disease Consortium (RLDC) focused on rare pulmonary diseases. Together, these two research consortia have studied more than 15 rare lung diseases and associated conditions.

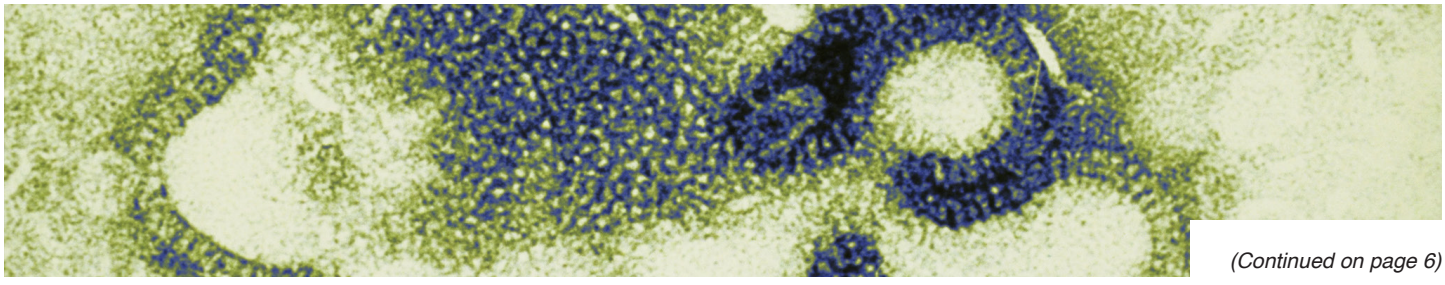
It Takes a Village

Over 25 million Americans and 300 million people worldwide suffer from one of 6,500 rare disorders. Despite the public health burden, research in rare disorders lags behind more common conditions and only 5-10 percent of all rare diseases have an FDA-approved therapy. Rare disorders present unique research challenges. For example, it is difficult to sufficiently power studies when there are few eligible participants. Additionally, patients tend to be geographically dispersed and diagnosis and patient identification may be hampered by lack of familiarity with rare disorders and insufficient data on the spectrum of disease presentation. Historically, research resources have been directed at more common diseases and very few rare disease patient communities have the financial wherewithal to fund their own research programs

Despite these challenges, interest in rare diseases research has drastically increased in the past two decades, partly because better communication and data sharing opportunities in the Internet age have allowed patient communities to organize and collaborate with interested researchers. Gene identification and access to genetic testing has improved diagnosis of many rare diseases and provided insight into potential therapeutic targets. As a result, industry has taken a more active interest, recognizing that rare diseases can often serve as natural laboratories for more common conditions.

In 2002 the Rare Diseases Act was signed into law, formalizing the mandate of Office of Rare Diseases Research by directing the NIH to accelerate research on rare disorders. To accomplish this directive, ORDR created the RDCRN, a comprehensive network of (now) 23 research consortia that connects researchers, NIH institutes, industry, external funders and patients and families. RDCRN consortia are designed to be collaborative, actively including all stakeholders, and to maximize impact by sharing resources among disorders with similar features. Data management for the entire network is centralized through another RDCRN consortium, the Data Management and Coordinating Center (DMCC), selected via a competitive grant process. The current DMCC is housed at Cincinnati Children's Hospital.

Active engagement of the patient community in all RDCRN activities is a hallmark feature of this network. Currently more than 140 patient groups representing 190 rare disorders participate in RDCRN activities. Patient representatives serve on RDCRN committees, provide



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Rare Diseases *(Continued from page 2)*

input on study design, assist with recruitment into RDCRN studies, fund collaborative initiatives, serve as co-investigators, and have their own patient-focused arm of the RDCRN called the Coalition of Patient Advocacy Groups (CPAG).

ATS: A Leader in Collaborating for Rare Disease Research Success

The American Thoracic Society has been a leader in encouraging collaboration with patient communities, including rare disease communities, to accelerate research. ATS Partner Grant opportunities, educational initiatives and membership in the ATS Public Advisory Roundtable (ATS PAR) are examples of the unique support patient communities have come to rely upon through ATS. Given this focus, it is not surprising that many groups that have successfully partnered with the RDCRN are also actively engaged in ATS activities, including serving on the ATS PAR, the patient arm of ATS. Former and current ATS PAR groups that also are member groups of the RDCRN include:

- Alpha-1 Antitrypsin Foundation
- ChILD Foundation
- Cystic Fibrosis Foundation
- Hermansky-Pudlak Syndrome Network
- LAM Foundation
- Lymphangiomatosis & Gorham's Disease Alliance
- NTMiR
- Primary Ciliary Dyskinesia (PCD) Foundation
- Tuberous Sclerosis Alliance

The continuing success of the RDCRN and the support of NIH institutes and professional societies like ATS offer hope for future treatments for individuals with rare lung diseases. For more information, visit:

- RDCRN Award Announcement: https://ncats.nih.gov/news/releases/2019/rdcrn-funding
- RDCRN: https://www.rarediseasesnetwork.org/

UNPROVEN STEM CELL TREATMENTS

Direct-to-Consumer Marketing of Unproven Cell-based Interventions for Respiratory Diseases: A Case of Deceptive Advertising?

By **Laertis Ikonomou, PhD, and Daniel J. Weiss, MD, PhD.**

Several cell populations, such as induced pluripotent stem cells, mesenchymal stromal cells, and endothelial progenitor cells, are being investigated at various stages of preclinical and clinical research for a variety of respiratory diseases and critical illnesses. As yet, there is no proven cell-based therapy for lung diseases that has been shown to be both safe and effective in well-controlled, sufficiently powered clinical studies[1]. However, there is a thriving industry that offers direct-to-consumer cell-based interventions, often advertised as innovative "stem cell" therapies, for a wide variety of diseases (neurological, musculoskeletal, respiratory, and autoimmune)[2, 3]. For respiratory ailments, the offered interventions use principally autologous cellular material, such as adipose tissue-derived stromal vascular fraction (SVF), bone marrow extract, and blood concentrate, including platelet-rich plasma (PRP), harvested from the patient and re-administered, usually intravenously. More recently, other unproven cell-derived preparations, such as extracellular vesicles, are increasingly offered. Nevertheless, this supposed wealth of therapeutic options is highly misleading, as weak or absent scientific rationale and absence of quantifiable patient outcomes are common characteristics of all these alleged treatments[1].

Despite universal opposition by pulmonologists, respiratory and thoracic societies, and lung disease patient foundations[2, 4], businesses engaging in direct-to-consumer marketing of unproven cell-based interventions do not show signs of abating their activities. Strategies utilized include, but are not limited to, extensive use

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Stem Cell Treatments *(Continued from page 5)*

of patient testimonies, registration of patient-funded studies to the federal ClinicalTrials.gov database[5, 6], and pressure on prospective patients to crowdfund or take up debt [7, 8] to create what has been aptly called "safe spaces for toxic stem cell marketing"[9]. Additionally, such businesses have a significant online media presence, from professionally designed websites to advertisement placement in search engines. For example, it has been reported that a business offering unproven cell-based interventions for lung diseases targeted vulnerable patient populations through carefully orchestrated online advertisement campaigns[10].

The gap between exaggerated advertising claims of safety and efficacy and the clinical reality of no therapeutic value may amount to deceptive advertising which in turn can be effectively used as an argument in either individual or class action lawsuits against businesses offering such interventions/products[11]. In the U.S., the Federal Trade Commission (FTC) has enforcement powers regarding consumer protection[12]. In its statement on deception, the FTC states that "…the Commission will find deception if there is a representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment"[13]. Recently, FTC took regulatory action, including refunds to patients, against a business offering unproven "stem cell" therapy for a wide variety of conditions that was unsupported by any scientific studies[14]. In a similar development, Google™ introduced a new policy "to prohibit advertising for unproven or experimental medical techniques such as most stem cell therapy, cellular (non-stem) therapy, and gene therapy" and stressed this new policy "will prohibit ads selling treatments that have no established biomedical or scientific basis". Google™ further clarified that this was in response to the "rise in bad actors attempting to take advantage of individuals by offering untested, deceptive treatments".

The recent emphasis on the deceptive character of unproven cell-based interventions is a welcome development, as it may pave the road for stronger regulatory and enforcement actions. Lung disease patients that feel defrauded by baseless therapeutic claims of unproven and unlicensed cellular therapies can and should file complaints with the FTC. A rise in federal enforcement combined with increase in patient-led lawsuits[10] may prove powerful disincentives for businesses seeking to capitalize on the pain and desperation of patients suffering from chronic lung illnesses. ■

RARE DISEASES

Genetic Disorders of Mucociliary Clearance Consortium Advances Care for Chronic Suppurative Respiratory Diseases

By **Thomas Ferkol, MD, ATS past-president**

Consisting of eight clinical research sites across North America, the Genetic Disorders of Mucociliary Clearance Consortium has focused on several inherited and acquired disorders that lead to chronic suppurative respiratory diseases and bronchiectasis. During the past 15 years, the Consortium has made numerous advances that profoundly changed diagnostic testing and clinical practice, particularly in primary ciliary dyskinesia, a rare, genetically heterogeneous disease characterized by chronic sinopulmonary infections, middle ear involvement, laterality defects, and reduced fertility. New insights into the genetics of primary ciliary dyskinesia have allowed us to define clinical features, revolutionize diagnostics, and revealed genotype-phenotype relationships.

The Consortium will continue to concentrate on rare, inherited forms of chronic suppurative respiratory diseases, but expand its focus to include primary immunodeficiencies, a broad, heterogeneous group of disorders that often share clinical features with primary ciliary dyskinesia. Partnering with patient advocacy groups, including the PCD Foundation and Immune Deficiency Foundation, the overarching goal of this multidisciplinary effort is to define genetic bases, pathophysiology and clinical manifestations, expand diagnostic capabilities, and identify novel therapeutic targets and endpoints for clinical

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trials that will ultimately improve outcomes for individuals with these rare, chronic suppurative respiratory disease.

For more information regarding this program, please contact the principal investigators, Stephanie Davis, MD, ATSF (stephanie_davis@med.unc.edu) and Thomas Ferkol, MD, ATSF (ferkol_t@wustl.edu), or the NHLBI program officer, Marrah Lachowicz-Scroggins, PhD (marrah.lachowicz-scroggins@nih.gov). ■

NIH

Proposed Changes to NIH Sexual Harassment Reporting Would Affect Grantees

By **Jennifer Ingram, PhD, member, ATS Research Advocacy Committee**

The #MeToo movement has fueled increased awareness of the negative impact of sexual harassment in the workplace. Research institutions, scientific centers and laboratories are not immune from the detrimental consequences of a work climate that allows for harassment and bullying. To change this culture of sexual harassment in scientific research and to protect vulnerable trainees, visiting scientists and other individuals, the National Institutes of Health recently convened a Working Group on Changing the Culture to End Sexual Harassment. The charge of the Working Group was to review current policies for reporting sexual harassment allegations as well as suggest changes for accountability at NIH-funded institutions and NIH-supported research conferences. The Working Group submitted their report on Dec. 12, 2019, and they made several recommendations that would directly affect how awardees report this information.

In the report, the Working Group points out that sexual harassment is a form of professional misconduct that negatively affects the research process and the advancement of science. Furthermore, the Working Group states that "the best path to eliminating sexual harassment is through fostering transparency, accountability, integrity, equity, and justice in the research environment." Thus, they suggest that academic institutions should: 1) consider sexual harassment allegations as seriously as research misconduct allegations; 2) develop plans to restore the careers of sexual harassment victims and other affected individuals; and 3) work to make the research environment safe, diverse and inclusive. They further assert that the NIH should make system-wide changes that promote better science by increasing diversity, reducing bias and recognizing the contributions of all researchers.

Among the specific recommendations that the Working Group made, several would affect individual NIH grantees. The Working Group recommends the following:

- NIH-supported institutions should be required to report any findings of violations of professional codes of conduct or sexual harassment or the reason for any change in status (leave of absence during a sexual harassment investigation) by principal investigators or key personnel on NIH-funded grants to the NIH within two weeks.
- The institution would be required to transition the support of any research staff affected by the change in status of a PI under investigation or terminated due to a finding of sexual harassment to another "safe-harbor" PI at that institution.
- Establish a hotline and/or website form that would allow all NIH-supported research staff, trainees, PIs and key personnel to directly report sexual harassment behavior and professional misconduct to the NIH anonymously or non-anonymously.
- The NIH should exclude all individuals with confirmed findings of sexual harassment from participation in Study Sections and Advisory Councils/Committees.
- On grant applications, the PI and all key personnel should be required to attest that they have not violated their institutions' code of professional

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NIH (Continued from page 7)

conduct or been found to have committed sexual harassment in the past and that they will abide by the professional code of conduct during the award period.

- NIH-funded personnel should be required to include a section in their biographical sketch that lists ways that they have contributed to safe, inclusive and diverse work environments, with the PI required to explain how they created a safe training environment in all annual reports.
- A Mentor Training Plan and Professional Conduct Plan would be required on applications for all NIH funding mechanisms.

The Director of the NIH, Francis Collins, MD, PhD, issued a statement on Dec. 12, 2019 with regards to the report. He stated that combatting sexual harassment in the biomedical sciences is a major priority for the NIH and that indeed, some of these recommended policy changes have already been implemented. Specifically, a webform has been established for anyone in the biomedical research community to report instances of sexual harassment to the NIH directly and anonymously. Furthermore, several other recommendations will be realized in the coming year, such as creation of new funding opportunities to benefit those individuals whose careers have been disrupted by sexual harassment. But, many of the report recommendations are still being considered for policy changes in the future and will require partnership between the NIH and NIH-supported institutions to fully employ improvements in the system.

The American Thoracic Society recently conducted our own review of Society policies with regards to professional misconduct. In 2019, the ATS Ad Hoc Task Force to Review the ATS Code of Conduct Policies and Procedures recommended several changes to the ATS member Code of Conduct, focusing on ways to address sexual harassment.

The revised Code of Conduct is now available on the ATS website, and it specifically states that ATS members must refrain from sexual harassment during any ATS-sponsored activity. For example, all individuals who register for the ATS International Conference (members, nonmembers, staff, trainees, exhibitors, etc.) are now required to attest that they will comply with this Code of Conduct. Any member found to be in violation of this Code will be subject to possible sanctions, including suspension or termination of membership and/or eligibility to participate in ATS activities. Furthermore, the ATS now provides a secure, third-party-managed online mechanism for any individual to report violations of the ATS Code of Conduct anonymously, either by phone (866-294-9426) or web.

Both federal research funding agencies and scientific societies have realized that sexual harassment among the biomedical research workforce is a pervasive problem which disrupts promising research careers, reduces diversity and ultimately impedes scientific advancement. These recent efforts by the NIH and the ATS to address these issues will improve sexual harassment reporting and increase accountability and transparency at all levels to make safer environments for work and interactions with colleagues. ■

NEWS FROM PCORI

NHLBI Chief of Staff is PCORI's New Executive Director

Former NHLBI Chief of Staff and Senior Scientific Officer, Nakela Cooke, MD, will become the Patient-Centered Outcomes Research Institute's (PCORI), new Executive Director on April 15, 2020, taking over from Interim PCORI Executive Director, Josephine Briggs, MD.

Dr. Cook's research portfolio includes comparative effectiveness, racial/ethnic and sex/gender disparities in cardiovascular disease and health services research. She joined the NHLBI Division of Cardiovascular Sciences as a medical officer in 2008, where her work involved clinical trials, outcomes research and epidemiology. In 2013, she was appointed to Chief of Staff in the Office of the NHLBI Director, Gary Gibbons, MD, where she has led numerous initiatives including the institute's strategic visioning process and women's health research agenda. ■

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DISEASE PREVENTION RESEARCH

NIH Tobacco-related Disease Prevention Advances Highlighted

The NIH's Office of Disease Prevention (ODP) recently released its Spotlight on 2019 report (PDF) showcasing key achievements over the past year. The ODP works to develop collaborative trans-NIH projects to address prevention research needs and one of its strategic priorities is to advance tobacco regulatory and prevention science.

Among the Office's accomplishments highlighted in the Spotlight report is creation of a new prevention subgroup of the NIH's Tobacco and Nicotine Research Interest Group (TANRIG) to address gaps in tobacco-related disease prevention research. The subgroup has released several research opportunities over the past two years to support studies on electronic nicotine delivery systems (ENDS) exploring the central mechanisms of effects in preclinical and clinical studies; and population, clinical, and applied prevention research.

The office collaborated with the TANRIG in 2019 to hold a workshop aimed at accelerating the development of quality and standardization of measurement related to ENDS-use behaviors and laboratory assays of ENDS products. The workshop's working group is now drafting recommendations for the assessment and reporting of ENDS measures, a critical step towards establishing measures for ENDS-associated studies.

Lung Cancer

The Spotlight report highlights lung cancer screening as an important earlier NIH disease prevention success story that has improved outcomes for Americans with lung cancer. The report notes that the National Cancer Institute's National Lung Screening Trial (NLST) helped provide the evidence base for the U.S. Preventive Services Task Force's (USPSTF) to revise its statement on lung cancer screening in 2013 to recommend low-dose computed tomography (LDCT) annually for adults between the ages of 55 and 80 with a history of smoking.

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ATS FOUNDATION

President's Message: ATS Welcomes Fundraising for the Research Program into the Fold

By **James Beck, MD, President, American Thoracic Society**

Since its establishment in 2004, the ATS Foundation has awarded over $19 million in research grants to over 260 deserving investigators in pulmonary, critical care and sleep medicine. We should all be proud of the research a program's achievements, as these investigators have gone on to receive over $330 million in federal funding.

At the Dec. 2020 Board of Directors Meeting, the Board voted unanimously to fold ATS Foundation fundraising operations into the ATS. This action was taken following several months of in-depth assessment of existing operations and exploration of how we might improve efficiency while also boosting fundraising to support the Research Program. The Board approved a change in the ATS Foundation governance structure, converting it to an ATS committee.

When it was originally established in 2004 it was anticipated that the Foundation would eventually be self-sustaining. However, despite the strong leadership of the Board of Trustees and efforts of the staff, ATS has continued to underwrite 100 percent of Foundation operations through 2019, in addition to contributing to the research fund annually. Furthermore, supporting the Foundation required significant duplication of ATS operations, for example, maintaining two sets of books for accounting purposes, conducting two financial audits every year, hosting separate websites, and added legal fees. In addition, there was frequent confusion among our donors as to the differences between the Society and ATS Foundation, with many making contributions to the former when they were intended for the latter.

Given that, we asked whether there was a more efficient, impactful way to raise funds to support the ATS Research Program, which continues to be a key Society priority. After careful consideration and consultation between the ATS Executive Committee and ATS Foundation Board of Trustees, we decided that folding the Foundation into the ATS would be most beneficial for all concerned, including donors and, most especially, the Research Program and the early career investigators it supports. We are very gratified that the Board voted unanimously to support this decision.

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President's Message *(Continued from page 10)*

What will this transformation look like? Here are the highlights:

- The Foundation will be replaced by the ATS Funds for the Future Committee which will operate within the existing ATS committee structure.
- The committee will be comprised of former members of the Foundation Board of Trustees who wish to continue to serve in a research program fundraising capacity. Dean Schraufnagel, MD, ATSF, will continue as chair of the committee.
- There will continue to be a strong firewall between the Funds for the Future Committee, which raises funds, and the Scientific Advisory Committee, which evaluates and awards grants. No ATS member can sit on both committees and different staff support each committee.
- 100 percent of funds raised to date by the Foundation as well as those raised in the future will support research, as the donors intended.
- Existing fundraising programs, such as the Funds for the Future Campaign and the Benefit at the International Conference, will continue as before.

It's important to emphasize that ATS support for research remains unchanged. At the same time, I am optimistic that this transformation, in addition to saving money, will streamline operations and allow us to amplify our fundraising ability, by tapping more fully into existing ATS staff and resources.

Finally, on behalf of the Executive Committee I would like to thank Dr. Schraufnagel, chair of the ATS Board of Trustees, and Linda Nici, MD, the vice chair, for their leadership on this issue and the entire Board of Trustees for their support.

I'm very proud of the Society for taking such a bold step to improve operational outcomes, and for finding a way to better utilize existing staff and resources. It's very exciting to watch the Society meet new challenges, and particularly rewarding to know that these changes are contributing to a solid base from which the Society will continue to support research for years to come.

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2019 - 2020 ATS Research Program Awardees

The ATS Research Program is pleased to announce the grant and award recipients for the 2019 grant cycle. The support of our members, donors, and partners make these awards possible—thank you!

- Nicholas Arger, MD - University of California, San Francisco
  ATS/Foundation for Sarcoidosis Research Grant - $80,000
  Single Cell RNA Sequencing of High T-bet-expressing T Cells to Determine Their Role in Sarcoidosis
- Jason Boehme, MD - University of California, San Francisco
  Pulmonary Hypertension Association Barst Fund Grant - $50,000
  Pulmonary Vascular Smooth Muscle Metabolic Reprogramming in Congenital Heart Disease
- Claude Farah, MBBS, PhD - The Woolcock Institute of Medical Research, Australia
  ATS/ResMed Research Award in Remote Monitoring and Management of COPD - $100,000
  Home Telemonitoring and Predictive Analytics of Lung Function for Management of COPD
- Lynn Fussner, MD - The Ohio State University
  ATS/Alpha-1 Foundation Research Grant - $80,000
  Impact of Alpha-1 Antitrypsin Genotype on Anti-PR3 IgG Epitope Specificity and Activity
- Rahul Kumar, PhD - University of California, San Francisco
  ATS/Pulmonary Hypertension Association Research Fellowship - $80,000
  Crosstalk Between Bone Marrow Compartment and Inflamed Lungs in Hypoxic Pulmonary Hypertension
- Donald Sullivan, MD - Oregon Health & Science University
  ATS/American Lung Association - $100,000
  Improving Decision Making in Lung Cancer: A Low-literacy Conversation Tool
- Ke Yuan, PhD - Boston Children's Hospital
  The Aldrighetti Research Award for Young Investigators - $80,000
  Pericytes as a Source of Smooth Muscle Cells in PAH: Role of HIF2a/CXCL12 Signaling
- Deepthi Alapati, MBBS - Nemours/Alfred I duPont Hospital for Children
  Optimizing Airway Delivery of CRISPR-Cas9 Gene Editing Reagents Using Non-viral Vectors
- Maurizio Chioccioli, PhD - Yale University
  A quantitative framework for diagnosing ciliary beating defects in Primary Ciliary Dyskinesia
- Raghu Chivukula, MD, PhD - Massachusetts General Hospital
  Mechanistic Analysis of Dysfunctional Lysosomes in Hermansky-Pudlak Syndrome
- Alex Gileles-Hillel, MD - Hadassah Medical Center, Jerusalem, Israel
  Counteracting Intermittent Hypoxia-Induced Adipose Tissue Dysfunction via VEGF-Mediated Angiogenisis
- Robert Guzy, MD, PhD - University of Chicago
  FGF Regulation of Myofibroblast Differentiation in Pulmonary Fibrosis
- Mark Hepokoski, MD - University of California, San Diego
  Extracellular Mitochondrial DNA in ARDS Due to Sepsis
- Edy Kim, MD, PhD - Brigham and Women's Hospital
  mTOR Drives Post-Sepsis Immunosuppression
- Jinho Kim, PhD - Stevens Institute of Technology
  Regeneration of Donor Lungs Refused for Transplantation Through Targeted Cell Replacement
- Sydney Montesi, MD - Massachusetts General Hospital
  Collagen-targeted PET Imaging in Idiopathic Pulmonary Fibrosis
- Crystal North, MD - Massachusetts General Hospital
  Environmental Influences on Respiratory Disease: Interactions between Air Pollution and HIV

- Sarah O'Beirne, MD, PhD - Weill Cornell Medicine
  Small Airway Biology Underlying Enhanced Female Susceptibility to Smoking-Related Lung Disease
- Franziska Rosser, MD, MPH - UPMC Children's Hospital of Pittsburgh
  Air Quality Index and Childhood Asthma: An Intervention
- Christopher Schmickl, MD, PhD - University of California, San Diego
  Rescuing OSA Patients Unable to Tolerate CPAP Using Endotype-Targeted Drug Therapy
- Daniel Schneider, MD, PhD - University of Michigan
  Influenza Modulates the Host Defense Function of Alveolar Macrophage-derived Extracellular Vesicles
- Anna Volerman, MD - University of Chicago
  An RCT of Virtual Teach-to-Goal versus Brief Instruction for Children with Asthma in Clinics
- Gary Weissman, MD - University of Pennsylvania
  Human & System Factors Contributing to Delays in Antibiotics for Patients Suspected of Sepsis
- Matt Zinter, MD - University of California, San Francisco
  Metatranscriptomic Evaluation of Lung Health in Pediatric Hematopoietic Cell Transplant Candidates
- Ignacio Esteban, MD - Hospital Garrahan, Buenos Aires, Argentina
  Survival of Pediatric Patients with Spinal Muscular Atrophy in a Low and Middle-income Country

RESEARCH FUNDING

Trump 2021 Budget Proposes Deep Cuts to Health Research and Services Programs

On Feb. 10, 2020, President Trump released his proposed budget for fiscal year (FY) 2021. The proposal includes some significant funding reductions to health research and services programs, including a proposed $3 billion cut to the NIH and a proposed $2.4 billion cut to the EPA.

The following are proposed reductions in the President's FY2021 budget:

NIH

- A $3 billion cut from current FY2020 NIH funding of $41.6 billion to $38.6 billion. This proposed reduction of 7.2 percent would be distributed fairly equally across all NIH institutes, including the NHLBI.
- Proposal to shift the Agency for Health Care Research and Quality (AHRQ) to NIH, along with a $90 million reduction from current funding of $445 million to $355 million.
- Priority NIH research areas for the Administration include opioids, influenza research, HIV, tick-born disease research and pediatric cancer.

CDC

- A $693 million, or 9 percent, cut for the CDC, from current funding of $7.694 billion to $7 billion.
- The proposed elimination of CDC's Office on Smoking and Health, currently funded at $230 million. This elimination was proposed in the FY2020 budget and was rejected by Congress.
- A $52.8 million funding cut to CDC's National Institute on Occupational Safety and Health (NIOSH). Similar cuts to NIOSH have been proposed in the last 2 administration budgets and Congress has rejected them.
- Elimination of CDC's $20 million for climate change and health program. This cut has been proposed before and rejected by Congress.
- A $5 million funding cut to CDC's asthma program, from $30 million in FY2020 to $25 million
- Flat-funding for CDC's domestic TB program at $135 million

EPA, VA Research and USAID TB

- A $2.4 billion, or 26 percent, cut to the EPA, reducing funding from the current $9.1 billion to $6.7 billion for FY2021.
- A $39 million funding increase for the VA Research program, from the current $750 million to $787 million.
- A $35 million funding cut to USAID's global TB program, from the current $310 million to $275 million.

Context

Neither Republican nor Democratic leaders on the Hill have received the President's budget with enthusiasm. In normal times, the party of the President uses the Administration's budget as a starting point for budget development and Congress then develops the actual spending bills. It's fair to assume that party leaders on both sides will dismiss this budget and move forward to develop their own funding recommendations. The reality is that while a proposed $3 billion funding cut for NIH is a very disappointing step by the administration, we expect that Congress will reject this funding reduction just as it has with previous year's budgets. Similarly, we expect that programs like EPA and CDC will not see the high level of cuts proposed by the Administration. ■

References:

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1. Engelbrecht JP, McDonald EV, Gillies JA, Jayanty RK, Casuccio G, Gertler AW. Characterizing mineral dusts and other aerosols from the Middle East--Part 1: ambient sampling. InhalToxicol 2009; 21: 297-326.

2. Garshick E, Abraham JH, Baird CP, Ciminera P, Downey GP, Falvo MJ, Hart JE, Jackson DA, Jerrett M, Kuschner W, Helmer DA, Jones KD, Krefft SD, Mallon T, Miller RF, Morris MJ, Proctor SP, Redlich CA, Rose CS, Rull RP, Saers J, Schneiderman AI, Smith NL, Yiallouros P, Blanc PD. Respiratory Health after Military Service in Southwest Asia and Afghanistan. An Official American Thoracic Society Workshop Report. Ann Am Thorac Soc 2019; 16: e1-e16.

3. Pugh MJ, Jaramillo CA, Leung K-w, Faverio P, Fleming N, Mortensen E, Amuan ME, Wang C-P, Eapen B, Restrepo M. Increasing Prevalence of Chronic Lung Disease in Veterans of the Wars in Iraq and Afghanistan. Military medicine 2016; 181: 476-481.

4. Rivera AC, Powell TM, Boyko EJ, Lee RU, Faix DJ, Luxton DD, Rull RP, Millennium Cohort Study T. New-Onset Asthma and Combat Deployment: Findings From the Millennium Cohort Study. Am J Epidemiol 2018; 187: 2136-2144.

5. Jani N, Falvo MJ, Sotolongo A, Osinubi OY, Tseng CL, Rowneki M, Montopoli M, Morley SW, Mitchell V, Helmer DA. Blast Injury and Cardiopulmonary Symptoms in U.S. Veterans: Analysis of a National Registry. Ann Intern Med 2017; 167: 753-755.

Direct-to-Consumer Marketing of Unproven Cell-based Interventions for Respiratory Diseases: A Case of Deceptive Advertising? Page

1. Ikonomou L, Wagner DE, Turner L, Weiss DJ. Translating Basic Research into Safe and Effective Cell based Treatments for Respiratory Diseases. Ann Am Thorac Soc 2019; 16: 657-668.

2. Ikonomou L, Freishtat RJ, Wagner DE, Panoskaltsis-Mortari A, Weiss DJ. The Global Emergence of Unregulated Stem Cell Treatments for Respiratory Diseases Professional Societies Need to Act. Ann Am Thorac Soc 2016; 13: 1205-1207.

3. Turner L, Knoepfler P. Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry. Cell Stem Cell 2016; 19: 154-157.

4. Pulmonary Fibrosis Foundation. An update of stem cell/cell-based therapies for pulmonary fibrosis beyond the context of clinical trials. 2019 March 5 [accessed 2020 February 20]. Available from: https://www.pulmonaryfibrosis.org/docs/default-source/medical-community-documents/stemcellstatement_march2019ee6af5d09b5d6477b7e4ff000016512a.pdf?sfvrsn=8c37918d_6.

5. Turner L. ClinicalTrials.gov, stem cells and 'pay-to-participate' clinical studies. Regen Med 2017; 12: 705-719.

6. Wagner DE, Turner L, Panoskaltsis-Mortari A, Weiss DJ, Ikonomou L. Co-opting of ClinicalTrials.gov by patient-funded studies. Lancet Resp Med 2018; 6: 579-581.

7. Snyder J, Turner L. Selling stem cell 'treatments' as research: prospective customer perspectives from crowdfunding campaigns. Regen Med 2018; 13: 375-384.

8. Snyder J, Turner L, Crooks VA. Crowdfunding for Unproven Stem Cell-Based Interventions. JAMA-J Am Med Assoc 2018; 319: 1935-1936.

9. Sipp D. The malignant niche: safe spaces for toxic stem cell marketing. npj Regen Med 2017; 2: 4.

10. Wan W, McGinley L. Clinic pitches unproven treatments to desperate patients, with tips on raising the cash. Washington Post; 2019.

11. Horner C, Tenenbaum E, Sipp D, Master Z. Can civil lawsuits stem the tide of direct-to-consumer marketing of unproven stem cell interventions. npj Regen Med 2018; 3: 5.

12. FTC. A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority. 2019 October 2019 [accessed 2019 December 4]. Available from: https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority.

13. FTC. FTC Policy Statement on Deception. 1983 [accessed 2020 February 20]. Available from: https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf.

14. FTC. FTC takes aim at deceptive stem cell therapy claims. 2018 October 18 [accessed 2019 December 5]. Available from: https://www.consumer.ftc.gov/blog/2018/10/ftc-takes-aim-deceptive-stem-cell-therapy-claims.