

Research News Quarterly

SEPTEMBER 2019

In This Issue

Letter From the Editor – p. 1

Interview with FIC Director – p. 2

Changing Patterns of Addictive Drug Use: Consequences to Pulmonary Health and Opportunities for Research – p. 5

New Trump Administration Policies Restrict Fetal Tissue Research – p.7

NINR Acting Director Announces Resignation – p.10

ATS Hill Day: An Early Career Perspective – p.10

Health Research Funding Update – p.12

The ATS Foundation – Breathing Better Through Research – p.12

EDITOR

VEENA ANTONY, MD

Chair, Research Advocacy Committee

ADVISORY BOARD MEMBERS:

AMALI SAMARASINGHE, Ph.D.

Member, ATS Research Advocacy Committee

NUALA S. MOORE

Director of Government Relations

Letter from the Editor

Our feature article this month is an interview with the NIH's Fogarty International Institute Director Roger Glass, MD, PhD. In the interview, Dr. Glass discusses the institute's efforts to alleviate suffering from the leading infectious diseases, including tuberculosis (TB), and expand programs to address the rise of noncommunicable diseases (NCDs) such as COPD in low- and middle-income countries. Dr. Glass also discusses the FIC's efforts to increase global health research capacity and provides some guidance for careers in global health research.

Dr. Nora Volkow, MD, director of the National Institute on Drug Abuse (NIDA) has provided a special feature for the Quarterly on the pulmonary consequences of addictive drug abuse, as well as opportunities for collaboration with pulmonary researchers. Next, we have commentary from members of the Research Advocacy Committee (RAC), led by Thomas Mariani, PhD, on how the Trump Administration's restrictions on the use of fetal tissue will impact scientific research.

In other news from NIH, we have announcements on the impending retirements of the NINR acting director Ann Cashion, Ph.D., RN. Shifting to ATS research activities, RAC member Jennifer Brett-Alexander, MD, PhD, provides an early-career member perspective on the ATS annual Hill Day.

We round out the Quarterly with latest report from our Washington Office on federal health research funding, followed by an update from the ATS Foundation, including a list of all of our 2018 award recipients.

Sincerely,

Veena Antony, MD

Editor

Chair, Research Advocacy Committee



Roger I. Glass, M.D., Ph.D., director,
Fogarty International Center

ATS Research News Quarterly Interview with NIH Fogarty International Center Director **Dr. Roger Glass**

Dr. Roger I. Glass was appointed director of the Fogarty International Center in 2006. A world-renowned expert in rotavirus and cholera research, he previously spent 20 years leading the CDC's Viral Gastroenteritis Unit. Early in his career, he worked in the U.K. with Sir Richard Doll to study the linkage between smoking and lung cancer.

Q: What is your vision for the Fogarty International Center over the next five years?

A: While we must remain focused on the unfinished agenda of alleviating suffering from infectious diseases — such as HIV/AIDS, TB, and malaria — we're also expanding our research and training grant programs to address the rising tide of noncommunicable diseases (NCDs) in low- and middle-income countries (LMICs). In our most recent [strategic plan](#), we identify two new priorities. The first is to better integrate emerging technologies to advance global health research and training in LMICs. The second is to spur research to more quickly adapt proven interventions so they work effectively in low-resource settings — what we call implementation science.

The ubiquity of cellphones in developing countries provides unique opportunities to leapfrog technologies. For example, one of our grantees working in Uganda developed a mobile health platform for training, disease-screening, and data collection. That technology has been spun off into a start-up company that's producing products for the U.S., and has created a [cellphone app that uses video for directly observed therapy for TB patients](#), reducing the number of clinic visits needed and lowering costs. In South Africa, where TB is an epidemic, we're supporting studies of a [text messaging intervention](#) to better link patients diagnosed with TB to care and treatment services. We have many more mHealth and bioengineering-inspired projects in the pipeline and see this as a promising way to leverage technology and Artificial Intelligence to make up for the tremendous lack of health care workers in LMICs.

Another area we're investing in is building multidisciplinary teams that we believe are key to advancing science in the 21st century. For instance, we funded a group of architects and engineers to work with infectious disease researchers to find ways to slow the spread of TB in hospitals in South Africa and Peru. They're expanding on lessons learned from a previous project

(Continued on page 3)

Dr. Roger Glass Interview *(Continued from page 2)*

in Rwanda, where they [designed a TB facility in novel ways to maximize air flow and installed ultraviolet lights to deactivate TB bacteria](#).

To draw attention to the broad scope of lung diseases and their enormous global burden, my colleague and I recently published an overview in the Annals of the American Thoracic Society, "[International Approach to Environmental and Lung Health](#)." The Society provides important leadership on these issues in the U.S. and globally.

We believe by taking science where the problems are greatest, we improve health for everyone, including Americans. The rise of multi-drug-resistant TB — [with nearly half a million cases in 2016](#) — is a frightening development that threatens us all. Through clinical trials carried out in South Africa, where MDR-TB is common, a new treatment regimen was found to be effective and was [recently approved by the FDA](#) for use in the U.S. These kinds of breakthroughs are why it's critical that we develop research capacity globally, especially in LMICs, where the needs and scientific opportunities are great and resources are few.

Q: What is Fogarty doing to increase the capacity for respiratory disease research in low- and middle-income countries?

A: This is a vital area of global health research and Fogarty is continuing to build much-needed scientific expertise in a variety of ways. We're supporting research and training for TB researchers through a number of our programs and currently fund [more than 20 related projects](#) in LMICs, many supported through our [Global Infectious Diseases](#) research training program. Through our [NCD initiatives](#), we're developing LMIC research capacity in chronic obstructive pulmonary disease, lung cancer, and other topics. We also fund [research and training in tobacco reduction](#), which has resulted in data to inform policies that help reduce consumption and exposure, lowering the burden of lung cancer and other related respiratory problems caused by smoking. Through our [trauma and injury program](#), we're developing expertise in emergency care research, which in some cases involves study of resuscitation methods and other such issues.

We're also very proud of our [GEOHealth program](#), which is building expertise in environmental and occupational research and establishing seven regional research hubs in LMICs. Each project addresses health threats that are high priorities in their respective regions including [outdoor and household air pollution, pesticide exposures, environmental contamination, climate change](#), and other issues. Our goal is to create hubs that become internationally recognized focal points for collaborative research, data management, training, curriculum development, and policy support, in partnership with others in the region. The hubs have established, and will continue to foster, relationships with LMIC government agencies and NGOs to help translate findings into practice and policy.

Q: Particulate matter from household cooking fires is recognized as a significant cause of pulmonary disease. What impact have Fogarty and the NIH had in this field and how far do we yet have to go to decrease the significant morbidity/mortality associated with this exposure?

A: Toxic smoke from stoves and open fires used for cooking by over half the world's population prematurely kills nearly two million people each year, according to the World Health Organization. That's why the [NIH joined with the United Nations Foundation in 2010](#) to work toward ensuring cooking the daily meal would no longer be a health risk for women and children in LMICs. Since this is a [cross-cutting issue](#), Fogarty has provided leadership and coordination among the 27 NIH Institutes and Centers on this topic.

While development and rollout of clean cookstoves has proceeded at a lively pace, [there is little research to establish that they benefit health](#). Fogarty and the NIH have helped define the research agenda for this important issue. The NIH, in partnership with USAID, the CDC, the EPA, and the Clean Cooking Alliance, launched the [Clean Cooking Implementation Science Network \(ISN\)](#), hosted at Fogarty, to advance the science of uptake and scale-up of clean cooking technology in the developing world. The NIH is now funding the [first large-scale trial](#) to investigate whether the use of cookstoves that run on liquefied

(Continued on page 4)

Dr. Roger Glass Interview *(Continued from page 3)*

petroleum gas (LPG) improve air quality sufficiently to provide measurable health benefits and can be effectively adopted in real world situations. NIH-supported researchers are conducting a [randomized control trial of LPG cookstoves and fuel in India, Rwanda, Guatemala and Peru](#). U.S. investigators and collaborators in the trial sites are following pregnant women, their offspring, and older women to provide evidence of the impact this alternative fuel has on household air pollution, child health and development, and adult chronic diseases.

In addition, Fogarty has produced [training materials to develop expertise in indoor air pollution research](#). In 2012, [a three-day research training workshop](#) was held at the NIH featuring faculty experts from academia, nongovernmental organizations, the NIH, and other government agencies who gave lectures and hands-on demonstrations of cookstoves and emissions testing to approximately 20 trainee scientists from the U.S. and seven developing countries.

Q: What advice would you give a pulmonary, sleep and critical care medicine trainee that is interested in initiating a global health research project or transitioning to a career in global health research?

A: I'm a firm believer that early immersion in global health research is a powerful way to learn fundamental skills and begin building a network of colleagues, which is essential for career advancement. At Fogarty, we've provided [year-long fellowships](#) for MD, PhD, veterinary students and postdocs so they can design and conduct a research project in an LMIC, with mentorship from an established scientist. This has proven to be a career-changing experience for many of the participants.

When the program began, it largely supported infectious disease trainees. Over time, we have greatly expanded its scope, and [recent Fogarty fellows](#) have expertise in numerous NCDs, engineering, law, and even landscape architecture. Several fellows have conducted research on thoracic-related issues. For example, one explored the [long-term health issues of intensive care unit patients with acute lung injuries in Peru](#). Another studied quick, liquid culture methods to [diagnose MDR-TB patients in Malawi](#).

From these modest investments in the next generation of global health leaders, we have seen great returns. Participants have published more than 300 articles in peer-reviewed journals and have presented research findings at numerous scientific meetings. Many have remained engaged in specific research questions important to their host countries long after the fellowships have ended — developing toolkits, starting nonprofits to provide funding, and continuing to share their expertise from afar. Several alumni have already secured independent NIH grants to continue their global health studies — one of our highest measures of success.

Details on [how to apply](#) for this and other [Fogarty research and training programs](#) are available on [our website](#). ■

RESEARCH NEWS QUARTERLY SPECIAL FEATURE - NIDA

The All of Us Research Program— Changing the Future of Health

By **Nora D. Volkow, M.D.**, Director, National Institute on Drug Abuse

While pulmonary health and addiction overlap across many topics, recent public health trends suggest several specific areas where research in respiration and lung health can help advance addiction science, and vice versa. Vaping devices, which are most frequently used to administer nicotine, along with the increases in consumption of cannabis driven by recent state-level policy shifts and marketing have created natural experiments, with some of the most vulnerable members of our population as test subjects. Meanwhile the opioid crisis and the rise in overdose deaths from opioid-induced respiratory depression underscore the need for collaboration between the addiction and respiratory research communities to find new overdose detection and reversal tools. In parallel, methamphetamine misuse is on the rise in our country, with pulmonary toxicity as one of its consequences.

Vaping

Even as we've made enormous strides in reducing cigarette use and lowering the incidence of lung diseases in the U.S., we are at the dawn of what could be a new public health crisis involving vaping technologies. Nationwide surveys, including the NIDA-supported annual [Monitoring the Future](#) survey, have shown rapid increases in vaping among adolescents, which have occurred within very short time periods. In 2018, 37.3 percent of high-school seniors reported vaping in the past year, and the percentage who reported past-month vaping of nicotine (not flavoring or other substances) nearly doubled, from 11 percent in 2017 to almost 21 percent in 2018. Some research has suggested that young people who use e-cigarettes are [more likely to progress to smoking](#) traditional cigarettes, thus threatening to undo the declines in youth smoking that have been so encouraging. Unfortunately, we still know very little about vaping's effects on lung health.

Preclinical research and a few human studies point to adverse effects on epithelial, endothelial, and immune cells of the lung when the propylene glycol and glycerol in e-cigarette fluid are heated and inhaled, as well as the aerosol's ability to [cause inflammation](#) and injure small airways. [Nicotine](#), present in varying concentrations in many products, appears to be independently toxic to the lungs. There are also concerns about [metals](#) produced from e-cigarette heating coils and about chemicals in flavorings, such as diacetyl and its chemical precursors, which can contribute to obstruction of the small airways ("popcorn lung"). Thus, while e-cigarettes may not produce the same dangers as traditional cigarettes, they may have their own unique risks. Of note, there are [recent reports](#) of acute pulmonary illnesses linked to vaping (including one fatality) from 14 states.

Cannabis

Ten U.S. states and Washington, D.C., have legalized cannabis for adult recreational use, and 20 additional states have broad-based medical marijuana laws. Surveys show cannabis use is increasing among adults. Despite the increased popularity of edibles and similar products, smoking the dried herb remains the most common mode of administration. [Smoked cannabis](#) irritates the lungs, and regular use is associated with increased pneumonia risk and chronic bronchitis. However, in contrast to tobacco, which constricts the airways, the THC in cannabis smoke has a bronchodilating effect. While small studies of smoked or vaped THC as a potential asthma therapy did not produce positive results, further research into possible therapeutic effects of THC in asthma may be warranted.

Research has not established a link between cannabis smoke and obstructive pulmonary disease, emphysema, and lung cancer. However, it is difficult to be confident in the conclusions from existing research due to the enormous variability among cannabis products and smoking behavior, the young age of participants in most studies, and difficulty controlling for co-use of tobacco. Cannabis use in adolescents, especially when initiated early, is highly associated with cigarette smoking and nicotine vaping. Steep increases in cannabis potency, which could affect use patterns, also limit the conclusions that can be drawn from older data. More and more teens are also vaping THC (the active ingredient of cannabis), and

Research News Quarterly Special Feature - NIDA *(Continued from page 5)*

the implications of this practice as regards the addictiveness or respiratory health effects of that drug remain to be seen. So, much more research is needed, to guide health care and help states and communities navigate this change drug landscape.

Opioids

Between 1999 and 2017, almost [400,000 people](#) died in the U.S. from overdoses involving prescription or illicit opioids. This epidemic has evolved in three waves, driven initially by prescription opioids, followed by heroin, and most recently by illicit synthetic opioids, mainly [fentanyl](#).

The deadly effects of opioids arise from the fact that mu-opioid receptors are abundant in parts of the brainstem controlling various respiratory functions. Opioid-induced respiratory depression involves a range of different processes including reduction in breathing rate and depth, depression of the respiratory response to hypoxia and excess CO₂, depression of the drive to breathe while awake, suppression of the pharyngeal muscle, and depression of the arousal response.

At present, naloxone is the only available medication for reversing overdose. But despite having a good safety profile, naloxone is not perfect, particularly when the overdose is caused by highly potent fentanyl and fentanyl analogs. Even when overdoses involving these substances are caught in time and reversed, multiple naloxone administrations are sometimes required. In addition, acute [chest wall rigidity](#) or “wooden chest syndrome,” which causes very sudden death, is coming under scrutiny as a contributor to opioid overdose mortality in some people who have injected fentanyl. More research is needed to understand its mechanisms and how to counteract it.

Overdose is not the only adverse health effect of opioid-induced respiratory suppression. [Central sleep apnea](#) is a common effect of taking opioids chronically for pain, affecting a quarter of patients. Since this type of apnea arises from opioids’ effects in the brainstem, the continuous positive airway pressure (CPAP) devices used to treat obstructive sleep apnea may not be effective or may even exacerbate the problem. [Adaptive servoventilation](#) devices that more sensitively adjust airway pressure have been studied, but more research is needed to develop central sleep apnea treatments for people prescribed opioids. The liabilities of

opioid analgesics have also created a need for new, safer pain treatments. Biased agonists at the mu-opioid receptor, for example, might produce pain relief without affecting the signaling pathways that lead to respiratory depression and reward. A [2018 study](#) found one such compound to be effective at controlling pain in nonhuman primates without those undesirable side effects.

Methamphetamine

While major public attention has focused on opioids because of their increasing lethality over the past two decades, methamphetamine has begun to be recognized as another emerging threat. National survey data show methamphetamine use increasing among young adults and overdoses due to methamphetamine have more than tripled in the past few years, both in the context of opioid exposure and in the absence of opioid exposure. Besides the risk of overdoses presumably secondary to fatal arrhythmias and cardiac ischemia, methamphetamine and other stimulant drugs are risk factors for [pulmonary arterial hypertension](#) (PAH), and the treatment prognosis when the condition is caused by drug misuse is worse than when it is idiopathic. Thus, providers need to know how to screen PAH patients for methamphetamine use. Patients receiving amphetamines for ADHD should also be monitored for PAH.

Collaboration between respiratory and addiction science is needed to advance the development of new treatments for patients suffering from drug-associated pulmonary pathology, including interventions that can prevent opioid-induced overdoses. It is also imperative that we develop a better understanding of the pulmonary effects associated with vaping, whether of nicotine or THC, including mechanism responsible for toxicity. Similarly, studies on the consequences of cannabis smoking in pulmonary health and interventions to treat lung pathology — whether from cannabis, vaping, or methamphetamine use — are needed. Finally, as we struggle to contain the fatalities associated with the opioid crisis, research at the intersection of pulmonary physiology and drug brain pharmacology might lead to new ways for preventing and treating overdoses. The respiratory research community can play a critical role in advancing these areas of science and in guiding clinical practice and policy. ■

Human Fetal Tissue Research and Regulation: Impact on Pulmonary, Critical Care, and Sleep Medicine

By Denise Al Alam, MD, Claude Jourdan Le Saux, PhD, Jennifer L. Ingram, PhD, Thomas Mariani, PhD, Nuala Moore, MA, Daniel J. Weiss, MD, and Michelle Yu, MD

In early June 2019, the Trump Administration announced [a new policy](#) banning intramural NIH human fetal tissue research. While the ban only halted intramural research (approximately three projects), it also included a requirement for new ethics reviews of NIH extramural fetal tissue research (about 200 ongoing projects). In addition, on July 26, the NIH issued [new guidelines](#) regarding human fetal tissue research in extramural grant applications, specifying the need to justify the use of these tissues, and the establishment of a new ethics board to review and approve their use. On June 5, in response to the Administration's policy, the American Thoracic Society issued a press release expressing concern about this ban, and its potential impact on research to advance cures for respiratory, critical care, and sleep disorders. The purpose of this article is to educate ATS society members about the ban on intramural NIH fetal tissue research and new NIH guidelines, their potential impact, as well as the past and current benefits of human fetal tissue research.

Relationship to restrictions on human embryonic stem cell research.

In the context of the ban on use of human fetal tissues for use in intramural biomedical research, including respiratory research, it is important to make a clear distinction between fetal tissues and embryonic stem cells (ESCs). ESCs are derived from blastocysts that represent fertilized eggs that have undergone several rounds of division in in vitro tissue cultures settings. In the U.S., these are produced in and obtained from in vitro fertilization (IVF) clinics, and are specifically those that are not utilized clinically and are donated for research purposes under strict regulatory guidelines. ESCs are not

fetal tissue obtained from terminated pregnancies, the subject of the current ban. Fetal tissue includes stem cells derived from placenta, amniotic fluid, and umbilical cord in addition to organ-specific tissues, such as fetal lung and liver; all of which would seem to fall under the new restrictions. Both ESCs and fetal tissues are powerful, yet different, complementary tools that have proven indispensable for major advances in understanding respiratory and other diseases, such as Cystic Fibrosis, HIV, Alzheimer's, spinal cord injury, and ocular diseases.

The use of human ESCs in biomedical research has also stimulated extensive and intensive ethical, moral, religious, and political discussions, as well as a temporary ban on use of federal funding for study of human ESCs during the administration of George W. Bush, a ban overturned by the Obama administration. The focus of the current ban is on human fetal tissues, separate from ESCs. The ATS has previously published [an official statement](#) supporting study of ESCs.

The policy/ban and related legislation.

The Administration's June 2019 policy states that intramural NIH researchers will not be permitted to acquire additional fetal tissue for research studies, effectively ceasing these and any future intramural studies. In addition, one large extramural study on HIV therapies at the University of California-San Francisco has been halted, interrupting a 30-year partnership between UCSF and the NIH. Current extramural studies using fetal tissue research will not be immediately affected or undergo additional review until renewal.

In response to the Administration's new restrictions on fetal tissue research, the U.S. House of Representatives passed an amendment sponsored by Rep. Pocan (D-WI), to the Fiscal Year (FY) 2020 health research and services spending bill that would prevent the Administration from imposing new ethics reviews on all federally-funded extramural research, by a vote of 225 – 193. In an effort to preserve the integrity of NIH's peer review system, the amendment would prevent new ethics reviews of all NIH studies, not just those using fetal tissue research. At press time, the Senate had not yet voted on a similar amendment to the FY2020 health spending bill. The ultimate fate of the fetal tissue ethics board is now tied to the resolution of FY2020 government spending, which appears unlikely to be resolved until later in the fall of 2019.

Human Fetal Tissue Research and Regulation *(Continued from page 7)*

On July 29, 2019, the Administration detailed additional justification and ethics review that, barring Congressional override, extramural researchers using fetal tissue will be required to undergo in grant applications submitted after Sept. 25, 2019. Specifically, researchers will have to add a section to grant proposals that provides justification for use of fetal tissue, describes that there is a lack of alternatives, and lists the methods and pre-existing data used to determine the lack of such alternatives plans. The proposal will also have to include plans for the use and disposal of human fetal tissue after completion of research, and details of how the tissue is obtained, including written informed consent and lack of enticements/benefits offered to patients to undergo abortion or donate the tissue. This justification will be subject to application page limits, and will also undergo a separate review by an undefined newly established “ethics panel” prior to funding. The composition of the ethics committee, and the role of such a committee in evaluating proposals, is not completely clear. Importantly, early-career researchers applying for NIH training awards will not be permitted to use fetal tissue from elective abortions in research.

Past contribution of human fetal tissue research.

In 2014, the NIH spent approximately \$75 million on human fetal tissue research, about half of total spending on ESC research.¹ A majority of these projects focused on HIV and other infectious diseases with respiratory involvement. Historically, cell lines derived from human fetal tissues are a major source for viral vaccines, including those for hepatitis A, varicella, zoster, measles/mumps/rubella and rabies. In fact, these vaccines are typically derived from the MRC-5 and WI-38, both lines originating from human fetal lung tissue. It is estimated that the approximately 6 billion doses of vaccines developed from these lines have prevented nearly 11 million deaths and 4.5 billion cases of disease.²

Beyond vaccine development, there has been broad utility to the use of human fetal tissues, and cells derived from these tissues, in infectious disease research. Just one example is the generation of rodent models with humanized immune systems.³ These animals can be used to study uniquely human diseases such as those resulting

from infection with HIV, including respiratory and non-respiratory (e.g., liver) complications. However, generations of this important de novo (non-heritable) model requires the continuous need for human fetal tissues, thus, a ban on fetal tissue research would eliminate this groundbreaking research tool.

More than one third of federally funded research using human fetal tissues aims to further our understanding of fundamental aspects of human development and developmental-related disorders.⁴ Despite some basic similarities, fundamental differences exist between developmental pathways in humans, rodents, and other animal models. Therefore, for many decades, human fetal tissue has been used in many areas of research to understand human organ development. Historically, the largest body of work in respiratory research using human fetal tissue aims to help science better understand the developmental processes in the human lung, as well as derangements resulting in congenital anomalies. The use of human fetal lung tissue has also helped shed light on genetic and congenital lung disorders associated with chromosomal anomalies such as acinar dysplasia, alveolar dysplasia, trisomy 21, and cystic fibrosis. In many of these situations, there are no good alternatives to the use of human fetal tissue. For example, the mouse lacks chromosome 21, and hence, trisomy 21-associated lung anomalies cannot be accurately studied in a mouse model.

Potential impact on current human fetal lung tissue research.

There has been recent publicity about the beneficial use of adult progenitor cells in respiratory disorders, including mesenchymal stromal cells.⁵ While promising, none of these have yet provided new therapies. Conversely, the use of fetal tissues in lung diseases research is still at its early stages, and the number of investigators and projects using fetal tissues is increasing, particularly with new analytical techniques, such as gene mapping and single cell sequencing. Recent studies from groups in the US and Europe have highlighted important cellular and molecular features seen in the human fetal lung that we didn't know existed in the past.⁶ These advances would not have been possible without the use of human fetal

tissue, as alternative models (mouse, iPSCs or organoids) have failed to identify such differences.

Babies born severely prematurely (24-28 weeks of gestation) and exposed to oxygen (either low, moderate or high) are at higher risk of developing respiratory disorders, ranging from severe to mild bronchopulmonary dysplasia, asthma, and airway hyper-reactivity. Because there are no ideal animal models of asthma and airway hyper-reactivity that recapitulate human disease, researchers are using mid-gestation human fetal primary cells and/or tissues to investigate the effect of oxygen and other environmental factor exposures on lung development.⁷ Organ cultures from fetal human lung tissues have also been extensively used to understand the effect of different hormones, growth factors and other agents (e.g. drugs) on lung growth and cell/cell interactions during human lung development.⁸ Scientists have also used human fetal lung tissue in lung cancer studies.⁹

The ban on human fetal tissue use for intramural NIH researchers will result in the abrupt ending of ongoing projects and promising research that has been funded for many years in some situations. For NIH-funded extramural scientists, the new regulation for additional justification and ethics committee review represents an unnecessary burden and may restrict the potential for beneficial human fetal tissue research. While it is important to keep a high ethical standard in the use of all human tissues, this function is historically and adequately provided by local institutional ethics review boards. Also, this new policy appears designed to hinder the development of proposals with human fetal tissue research, considering that the extensive required justification has to be included within the page limit of grant proposals. While these rules do not make human fetal research impossible for established investigators, they do represent major obstacles.

Importantly, this new policy also makes it nearly impossible for trainees and early career scientists to use human fetal tissue in their NIH proposals by prohibiting the proposed use of human fetal tissue research in training awards and fellowships, including all T awards, pre-doctoral and postdoctoral fellowships, and career development awards. Trainees working in the laboratories

of established investigators will not be allowed to implement their novel ideas because of the limitations placed on their ability to obtain funding for research that uses human fetal tissue. Unfortunately, some of the most valuable tools for lung development research will be off limits to arguably the most productive and innovative investigators in pulmonary medicine. The ATS will continue to monitor policy developments in this area and support open access to fetal tissue for all federally-funded intramural and extramural scientific research and the integrity of NIH's ethics and peer review system. ■

1. Nature 528, 178–181 (10 December 2015)
doi:10.1038/528178a; <https://www.nature.com/news/the-truth-about-fetal-tissue-research-1.18960>.
2. <https://www.historyofvaccines.org/content/articles/human-cell-strains-vaccine-development>.
3. Melkus, M. W. et al. Nature Med. 12, 1316–1322 (2006).
4. Nature 528, 178–181 (10 December 2015)
doi:10.1038/528178a; <https://www.nature.com/news/the-truth-about-fetal-tissue-research-1.18960>.
5. [https://doi.org/10.1016/S2213-2600\(19\)30222-X](https://doi.org/10.1016/S2213-2600(19)30222-X).
6. Am J Physiol Lung Cell Mol Physiol. 2018;314(1):L144-L9; Elife. 2017;6. Epub 2017/07/01. doi: 10.7554/eLife.26575. PubMed PMID: 28665271.
7. Am J Physiol Lung Cell Mol Physiol. 2012;303(8):L711-9; Am J Physiol Lung Cell Mol Physiol. 2014;307(12):L978-86).
8. Pediatr Res. 1997 Sep;42(3):356-64; Development. 1996;122(10):3107-15).
9. Acta Histochem. 2015;117(4-5):451-9.

News From NINR

NINR Acting Director Announces Resignation

In late August, National Institute of Nursing Research (NINR) Acting Director Ann Cashion, PhD, RN, announced that she will retire from federal service on September 30, 2019. Dr. Cashion has served as acting director of NINR for the past year, following director Patricia Grady's retirement in August 2018, and as the institute's Scientific Director since 2013.

Prior to joining NINR, Dr. Cashion was professor and chair of the Department of Acute and Chronic Care in the College of Nursing, University of Tennessee Health Science Center (UTHSC). She joined NINR in 2011 as senior adviser to Patricia Grady, PhD, RN. As scientific director, Dr. Cashion created a successful intramural research program focused on advancing symptom science, a program that now includes the

NINR-led, [trans-NIH Symptom Science Center](#). In her August [Director's Message](#), Dr. Cashion stated that she intends to return to her family in Tennessee following her retirement from government service.

The NIH will be re-opening the search for a new permanent Director of NINR shortly. Following Dr. Cashion's departure, NIH Principal Deputy Director Lawrence A. Tabak, DDS, PhD, will serve as acting director of the institute. Additionally, NIH Associate Deputy Director Tara A. Schwetz, PhD, will serve as NINR's acting deputy director, from Aug. 26, managing the daily operations of NINR. Jessica M. Gill, PhD, RN, FAAN, currently NINR's deputy scientific director, will serve as the acting scientific director. ■

ATS MEMBERS IN ACTION

ATS Hill Day: An Early Career Perspective

By Jennifer Brett-Alexander, M.D., Ph.D., Member,
ATS Research Advocacy Committee

I'm contributing this article to share my experience with ATS Hill Day as an early career physician-scientist, which I hope will encourage other junior faculty to engage in research advocacy, as well.

For perspective, I'd first like to detail some personal experiences that motivated my participation in Hill Day. As a young person, my outspoken personality was frequently employed to advocate on behalf of whatever social issue captured my interest at the moment. In high school I participated in the Close Up program in Washington D.C., which afforded me the opportunity to observe the democratic process on Capitol Hill firsthand. This

experience solidified my interest in advocacy and encouraged my subsequent participation in national and community-based science outreach programs and medical advocacy groups.

In the Fall of 2013, my passion for science advocacy was recharged. At the time, I was a postdoctoral fellow and had been successfully engaged in research encompassing my undergraduate and graduate training for more than 15 years. I had just submitted my fellow-to-faculty K08 application and was encouraged about my potential for securing mentored funding. Up to that point, the majority of my time in the lab was spent during a relatively stable funding climate. But the tide was changing, and D.C. was in turmoil. Recall this was the time of looming enactment of sequestration funding. The NIH budget had been drifting down from a peak in 2002 and the K series success rates were hovering near 20 percent. Then, my worst fears were realized when I awoke on Oct. 2, 2013 to learn the federal government had "shut down" a few weeks before my scheduled grant review. As days passed with no resolution, I waited in agony. With mere days to spare, the government finally re-opened and I learned my meeting would proceed as

ATS Members in Action *(Continued from page 10)*

scheduled. Others submitting that cycle were not so fortunate. I held my breath through the enactment of the budget sequester and ultimately received my notice of award. After riding this roller coaster of emotions, I felt compelled to get back to D.C. and engage legislators directly about the critical need for stable science funding.

I later joined the ATS Research Advocacy Committee and participated in my first Hill Day in March 2019. I was fortunate to work with a fantastic group including Stuart Sweet MD, PhD, from my home institution, Don Hayes MD, MS, from Ohio State, Humberto Choi MD from Cleveland Clinic and Greg Porta, co-founder of the ChILD Foundation and our patient advocacy representative. Those of us participating in our first Hill Day were fortunate to be paired with Stuart and Greg, who are seasoned advocates. Both are active in government engagement and have been participating in ATS Hill Day for

years. Navigating the Senate and House office buildings can be challenging, and they knew their way around Capitol Hill in every sense.

We enjoyed meeting with representatives from both Missouri and Ohio and sharing our perspectives on issues important to our patients. I particularly enjoyed the opportunity to visit the office of Senator Roy Blunt, the Chairman of the Senate Appropriations Committee for Health and Human Services. It was truly empowering to speak directly with his staff about the critical role of NIH funding in launching the careers of junior scientists and maintaining the pipeline for future discoveries. Overall, Hill Day was a fantastic experience and well worth the time spent. I look forward to the next ATS Hill Day and hope to meet new ATS early-career members who are interested in advocating for research. ■



Pictured (left to right): Greg Porta, Stuart Sweet MD, PhD, Jennifer Alexander-Brett MD, PhD, Humberto Choi MD, Don Hayes MD, MS.

RESEARCH FUNDING

2020 Health Spending Bill May Face Funding Reductions

Congress returns to Washington on September 9, 2019, just a few weeks ahead of a September 30 deadline for finalizing fiscal year (FY) 2020 government spending, including for the NIH and CDC. It is looking likely that Congress will not be able to meet this deadline to finalize all twelve spending bills and will instead have to pass a short-term spending measure in order to avert a government shutdown. It is reported that Senate appropriators are preparing a short-term government spending to fund government programs until just before Thanksgiving.

In July, the full House of Representatives passed its FY2020 health spending bill which included a \$2 billion funding increase for NIH. However, news emerged in August that \$4 - \$5 billion may be cut from the Senate's 2020 Labor-Health and Human Services spending bill, which includes the health spending measure, in order to fund a border wall. If true, this action would endanger the proposed \$2 billion funding increase for NIH and will set up a conflict between the House and the Senate over FY2020 spending. ATS will monitor developments with FY2020 health spending closely and continue to advocate for a \$2.5 billion funding increase for NIH and a \$900 million increase for CDC in 2020. ■

ATS FOUNDATION UPDATE

The ATS Foundation – Breathing Better Through Research

The ATS Foundation was established in 2004 to provide seed grants to early career investigators in respiratory medicine whose careers were challenged by severe cutbacks of federal funding for research. Since its inception, 263 awardees have been granted \$19.4 million and gone on to secure \$330 million in awards as principal investigators

from the National Institutes of Health, among other public and private funders. For our benefactors, this translates into a return of investment of \$17 for every dollar awarded. In 2018, donors from the ATS community, membership, nonprofits, and industry partners provided \$2,700,000 in support with \$444,230 raised from the Annual Foundation Research Program Benefit alone.

With funding from the ATS Foundation, our research awards have changed scores of professional lives and is poised to transform respiratory medicine to the benefit of the millions suffering from various respiratory diseases. Our awardees have gone on to publish in prestigious journals and have transitioned to careers as senior investigators, and as mentors they now share their expertise with a new generation of researchers in turn.

Notable awardees include Charles A. Powell, MD, Chief of Pulmonary, Critical Care and Sleep Medicine at Mount Sinai in New York and CEO of the Mount Sinai-National Jewish Health Respiratory Institute, and Darrell Kotton, MD, who established the Center for Regenerative Medicine with 31 scientists and a commitment to “open source biology”.

Other core programs funded through the Foundation include the Methods in Epidemiologic, Clinical, and Operations Research (MECOR) Program for global health; Medical Education Research, a new program supporting novel curricular approaches; the Ziskind Clinical Research Scholar Award, the Mellins Award, and ATS Assembly Awards and Scholarships.

Research Program Awardees in 2018 include:

David Geoffrey Chapman, BSc, PhD - University of Technology Sydney

ATS Foundation/ResMed Research Fellowship in Sleep Disordered Breathing and PAP Therapy - \$100,000

Zhiyu Dai, PhD – University of Arizona

The Aldrighetti Research Award for Young Investigators - \$80,000

Ross G. Edgar, BSc, MRes - University of Birmingham

ATS Foundation/Alpha-1 Foundation Research Grant - \$80,000

Shashi Kant, PhD - Baylor Research Institute

ATS Foundation/Insmmed Research Award in Non-Tuberculous Mycobacteria (NTM) Lung Disease - \$50,000

ATS Foundation Update *(Continued from page 12)*

Landon W. Locke, PhD - The Ohio State University

ATS Found/Mallinckrodt Pharmaceuticals Inc. Research Fellows. in Sarcoidosis - \$80,000

Brenda Marsh, MD, PhD - Oregon Health and Science University

ATS Foundation/American Lung Association - \$100,000

Neuroinflammatory Causes of Heritable Allergic Asthma: Examining the Role of TRPA1

Michael Podolsky, MD - University of California, San Francisco

ATS Foundation/American Lung Association Research Grant - \$100,000

Paul Andrew Reyfman, MD, MS - Northwestern University

ATS Foundation/Boehringer Ingelheim Pharmaceuticals, Inc. Research Fellowship in Idiopathic Pulmonary Fibrosis - \$100,000

Xin Sun, PhD - University of California, San Diego

ATS Foundation/Children's Interstitial Lung Disease Found. Research Grant - \$50,000

Spyridon Fortis, MD - University of Iowa

ATS Foundation/Fisher & Paykel Healthcare Ltd. Research Award in Respiratory Support with Nasal High Flow (NHF) in Patients with COPD - \$100,000

Soban Umar, MD, PhD - University of California, Los Angeles

ATS Foundation/Pulmonary Hypertension Association Research Fellowship - \$80,000

Nicole White, PhD - Washington University in St. Louis

ATS Foundation/American Lung Association Research Grant - \$100,000

Zhan Liang, PhD, RN - University of Miami

2018 ATS Foundation Nursing Research Award

Alessandra Adami, PhD - University of Rhode Island

2018 ATS Foundation Unrestricted Grant: Pulmonary

Thomaz A. Fleury Curado, MD, PhD - Johns Hopkins University, School of Medicine

2018 ATS Foundation Unrestricted Grant: Sleep

Laurie Christine Eldredge, MD, PhD - Seattle Children's Hospital and University of Washington

2018 ATS Foundation Unrestricted Grant: Pulmonary

Jegen Kandasamy, MBBS, MD - University of Alabama at Birmingham

2018 ATS Foundation Unrestricted Grant: Pulmonary

Luu Van Pham, MD - Johns Hopkins University, School of Medicine

2018 ATS Foundation Unrestricted Grant: Sleep

Seppo Rinne, MD, PhD - Boston University

2018 ATS Foundation Unrestricted Grant: Critical Care

Lokesh Kumar Sharma, PhD - Yale University

2018 ATS Foundation Unrestricted Grant: Critical Care

Ciara M. Shaver, MD, PhD - Vanderbilt University Medical Center

2018 ATS Foundation Unrestricted Grant: Pulmonary

Benjamin Singer, MD, PhD - University of Michigan Medical School

2018 ATS Foundation Unrestricted Grant: Critical Care

Huanxing Sun, PhD - Yale University

2018 ATS Foundation Unrestricted Grant: Pulmonary

Matthew Triplette, MD, MPH - Fred Hutchinson Cancer Research Center and University of WA

2018 ATS Foundation Unrestricted Grant: Pulmonary

Annelies Van Eyck, PhD - University of Antwerp

2018 ATS Foundation Unrestricted Grant: Sleep

Eszter Katalin Vlado, PhD - University of Colorado School of Medicine

2018 ATS Foundation Unrestricted Grant: Pulmonary

Xiaoyi Yuan, PhD - The University of Texas Health Science Center at Houston

2018 ATS Foundation Unrestricted Grant: Pulmonary

Yahong Chen, MD, PhD - Peking University Third Hospital, China

2018 ATS Foundation MECOR Award - \$5,000

Nazan Cobanoglu, MD - Ankara University, Turkey

2018 ATS Foundation MECOR Award - \$5,000

Feng Sun, PhD - Peking University, China

2018 ATS Foundation MECOR Award - \$5,000

Michael Liam O'Byrne, MD, MSCE - University of Pennsylvania

Robyn J. Barst, MD Pediatric PH Research & Mentoring Grant in Memory of London A. Lotarski - \$50,000

To learn more about the ATS Foundation please visit our website (<https://foundation.thoracic.org/>). ■