

Research News Quarterly

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Letter from the Editor

Our feature article this month is an interview with the NIH's National Institute on Aging Director Richard Hodes, MD. Dr. Hodes discusses how the institute is studying how the aging process affects the respiratory system, from specific diseases such as COPD and idiopathic pulmonary fibrosis to end-of-life and ICU care. Dr. Hodes also highlights the ATS Critical Care Working Group on Aging and Geriatrics, co-chaired by Nathan Brummel, MD, and Lauren Ferrante, MD, as an example of the institute's collaborative efforts with stakeholders.

We move to NIH for an update on the NIH's implementation of the new single IRB policy and other new clinical trials policies. Next up is a PAR profile of the Allergy and Asthma Network by AAN President and Research Advocacy Committee member Tonya Winders.

Moving to upcoming events, we share an announcement for the NIH's Rare Disease Day on March 1, 2018, a free annual event for patients and researchers. Next, we report on how California tobacco taxes are funding research on tobacco-related diseases and health disparities and supporting young investigators.

This edition of the Quarterly concludes with an update from the ATS Washington Office on health research and services funding.

Veena Antony, MD
Editor



INTERVIEW WITH National Institute on Aging Director, Richard Hodes, MD

Q: What is your vision for the National Institute on Aging over the next five years?

A: In short, our vision is to do everything we can, within the research mission of the National Institute on Aging, to enable all Americans to enjoy robust health and independence with advancing age.

From a research perspective, that means understanding the aging contexts for illness and health. And so, we are exploring aging not as a single process, but rather as an intricate web of interdependent genetic, biochemical, physiological, economic, social, and psychological factors.

NIA also serves as the lead NIH institute for research on Alzheimer's disease and related dementias. As these conditions have been recognized as a growing threat to the aging population, we've been extremely fortunate that Congress has appropriated additional funding specifically for research in these areas. A significant amount of funding, attention, and energy is focused on these conditions as we continue to capitalize on the scientific opportunities now before us.

Q: Given that lung diseases such as COPD are a major cause of morbidity and mortality, as well as a co-morbid condition in other diseases of aging, how is the NIA working to address these diseases?

A: While aging itself isn't a disease, we know that the aging process represents a major risk factor for several chronic diseases and conditions. As we grow older, we're more likely to be diagnosed with one or more chronic ailments, from debilitating conditions such as arthritis, fatigue, and frailty to life-threatening diseases, such as cardiovascular disease, chronic lung disease, diabetes, and cancer.

In the ATS's area of interest, the NIA is supporting research to better understand how the aging process affects the respiratory system. Among the questions we are pursuing: How does aging affect the lungs of smokers and former smokers compared with how it affects people who have never smoked? What is the structure and function of the "normal aged lung?" What effect does adult-onset asthma have on the lung and what is its relation to COPD? How do we balance treatment for chronic bronchitis and COPD, such as steroids and bronchodilators, with these medications' possible risk of worsening osteoporosis and heart disease, respectively? Can we treat idiopathic pulmonary fibrosis to reduce the incidence of increased mortality,

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Richard Hodes Interview *(Continued from page 2)*

both of which rise significantly with advanced age? As these projects move forward, we will be sharing the findings, with particular attention to disseminating those most immediately relevant for clinical practice.

Q: Does the NIA plan to increase collaborations with other institutes/organizations where there may be overlap on diseases of aging?

A: The NIA has an extensive track record of collaborating with other organizations to introduce or enhance the aging component of research in specific diseases. We collaborate regularly with our sister NIH institutes, participating in a wide range of funding opportunities with them. Specifically, the NIA participates on the COPD Federal Partners Interest Group, which recently drafted the [National COPD Action Plan](#). We also work closely with several aging-related organizations, associations, and professional societies. In addition to the [American Geriatrics Society](#) and the [Gerontological Society of America](#), which focus on age-related issues, we regularly participate in meetings and workshops of other professional groups who care for older patients.

For example, two early-stage NIA grantees recently spearheaded the establishment of the [ATS Critical Care Working Group on Aging and Geriatrics](#), co-chaired by Nathan Brummel, MD and Lauren Ferrante, MD. The group's goal is to establish a collaborative, interdisciplinary group of critical care experts with a focus on improving the health of older adults with critical illness. By integrating a geriatric perspective into ATS meetings and educational programs, we can learn more about how aging affects pulmonary function and vice versa.

One of the most exciting developments in this area in recent years is the emergence of the new concept of "geroscience." This interdisciplinary group seeks to understand the genetic, molecular, and cellular mechanisms that make aging a major risk factor and driver of several age-related diseases. Recent studies have suggested that targeting aging will at the same time slow the occurrence and/or lessen the burden of some diseases. This new look at the relationships between aging and disease has sparked great interest and new

collaborations within the NIH and with scientists around the globe. In 2015, the NIA held a workshop "Intersection of Aging Biology and Pathobiology of Lung Diseases" to explore these mechanisms.

Q: Since end-of-life issues are important as we age and so many health care dollars are spent in the last three months of life, are critical care issues and improving outcomes in the ICU important concerns at the NIA?

A: It's important for physicians, patients, and patients' families to communicate clearly and understand as much as possible about the specific consequences of intensive care interventions and expectations for recovery following ICU care. When older people are hospitalized for medical or surgical reasons, we know that it is crucial for the medical team to work with patients and families to determine the appropriate use of resources that will help to achieve a quality of life that is acceptable to patients and their caregivers. A recent NIA workshop summarized the current scope of and identified research gaps in palliative and end-of-life care in acute and critical care settings. Subsequently, the NIA issued [funding opportunities](#) to improve patient-caregiver-provider communication and goals of care in critically ill patients.

The NIA is currently supporting research in such areas as post-ICU syndrome, delirium, sepsis, and other conditions related to intensive care. By determining their pathophysiology, we can then look for interventions that will be of most benefit to patients. For example, the NIA is now funding a delirium network which connects interdisciplinary basic and clinical investigators and their resources to accelerate progress in elucidating underlying mechanism(s) of delirium and efforts to improve prevention, diagnosis, and management. We also support research to integrate the consideration of common age-related geriatric issues, including multiple comorbidities, polypharmacy, frailty, and cognitive decline into the care of critically ill patients and those with chronic lung disease, to improve individualized patient-centered outcomes.

Q: Resilience against diseases of aging and senescence is an important factor and is becoming recognized in

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Richard Hodes Interview *(Continued from page 3)*

pulmonary disease. Do you see this as an important area for further study?

A: Resilience has been shown to be a crucial component of health and aging—from the cellular to the clinical to the behavioral level. Several new studies are in progress, and we are [seeking applications](#) for additional investigations on this topic.

In basic research, we're looking at the ability of the cell and its components to respond to different types of stressors. In addition, cell senescence and the ability of the body to dispose of senescent cells have emerged as a key research areas. We're also supporting investigations in neuroplasticity and the brain's ability to recover and retain cognitive function.

In the clinical arena, we're looking at how different bodily systems respond to physical injury – from broken bones and injured organs caused by trauma to recovery from intentional stresses, such as surgery or drug therapies. By analyzing how different factors contribute to physical resilience, we may be better able to predict risk for and response to recovery from physical injury.

At the social and behavioral levels, we have an expanding portfolio on psychological resilience to adverse early-life experiences, along with response later in life to loss, hardship, and environmental stressors. One intriguing recent finding shows that individuals' perceptions of their positive well-being and life satisfaction translate into greater psychological resilience on individual and societal levels.

Q: What can the ATS and the pulmonary community of scientists and clinician scientists do to further recognize and elevate aging science in pulmonary disease?

A: Collaboration among clinical and scientific specialists in pulmonary disease is particularly important for moving care and science forward. As we seek to enroll older people into clinical trials on a range of diseases and conditions, clinicians can be ideal partners in raising awareness among geriatricians, pulmonologists, and patients about the clinical trials enterprise, and the role

for all of us in finding answers to critical questions. It's also important to promote communication between the research and clinical communities through attending and participating in workshops and conferences on topics of common interest. We can also work together to continue to highlight aging/geriatric issues at national meetings.

Q: Given that an increasing number of older people are cared for by subspecialists, who have limited background/training in geriatrics, how is the NIA working to address the research/training needs for geriatric subspecialties?

A: A decade ago, the Institute of Medicine published a report, "[Retooling for an Aging America: Building the Health Care Workforce](#)," which continues to be relevant today. The report analyzed the forces that shape the health care workforce for older people, including education and training, models of care, and public and private programs. The authors recommended a concurrent three-point approach:

- Enhance the geriatric competence of the entire workforce
- Increase the recruitment and retention of geriatric specialists and caregivers
- Improve the way care is delivered.

In recent years, in keeping with recommendations from the IOM report, the NIA has focused primarily on the first of these three recommendations. Our [GEMSSTAR – Grants for Early Medical/Surgical Specialists' Transition to Aging Research – Program](#) enables physicians just starting their careers to connect their specialty to aging research. We strongly encourage applications to this important clinical research program, which can provide for specific training activities, mentorship, networking with other specialists, and other career development opportunities.

We want to develop aging research capacity among physicians in other clinical specialties. By tackling a research problem that combines aging and their specialty, these clinicians can carve an important niche in their field. Ultimately, we see our GEMSSTAR grantees developing into future leaders in research

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that bridges their specialty and aging science. Details about GEMSSTAR and the [application process](#) are available on the NIA website.

Finally, the NIA is eager to form networks with the ATS and other specialty groups to provide training programs that enable geriatric specialists to collaborate with their colleagues. This can be made possible through a variety of NIH programs, including [NIA training and fellowship awards](#), conference awards, and newer infrastructure-building mechanisms. ■

NIH RESEARCH POLICY

NIH Implements Clinical Trials Policy Reforms, Including Single IRB

In Jan. 2018, the NIH began implementing a series of clinical trials reforms aimed at improving accountability and transparency in clinical research. The following changes that may impact some pulmonary, critical care, and sleep researchers took effect on **Jan. 25, 2018**:

- **Clinical trial-specific funding opportunities:** Applications and proposals involving clinical trials with **due dates on or after Jan. 25, 2018**, must be submitted in response to a funding opportunity announcement (FOA) or request for proposal (RFP) that explicitly states it will accept clinical trials. After Jan. 25, 2018, the NIH will only accept clinical trial applications when submitted to parent announcements or other FOAs that specify clinical trials.
- **New Human Subjects and Clinical Trial Information form:** The NIH will require a new application form that consolidates all information related to human subjects and clinical trials into one place, and also expands the information required for studies that meet the NIH definition of a clinical trial. **This form will be included in the new FORMS-E Application Packages to be used for all due dates after Jan. 25, 2018.**

- **Registering and reporting for NIH-funded clinical trials:** All NIH-funded clinical trials are now required to register and submit results information to ClinicalTrials.gov to help ensure that information about clinical trials and their results are made publicly available in a timely manner.
- **Clinical Trials Protocol Template for Phase II and III Clinical Trials Conducted Under an IND or IDE:** Investigators are encouraged to use a template and electronic protocol-writing tool, developed by the NIH and the Food and Drug Administration, to help evaluate the scientific basis of their assumptions, minimize uncertainty in the interpretation of outcomes, and prevent loss of data.
- **Good Clinical Practice Training:** The NIH expects all NIH-funded clinical investigators and trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice to help ensure the safety, integrity, and quality of clinical trials.

Single IRB Policy

The NIH's single-IRB policy aims to have domestic sites of all NIH-funded multi-site studies involving non-exempt human subjects research use a single IRB. NIH developed the policy to address growing concerns that site-specific IRB reviews of multi-site studies were creating substantial administrative burden, delay and increased costs on research without enhancing human subject protection. The single IRB policy is part of a larger NIH effort to improve the management, quality, and oversight of clinical trials and clinical research supported by the agency.

ATS Research Advocacy Committee chair Veena Antony, MD, says, "The single IRB will help overcome the delays commonly found in multi-institutional studies, which must obtain IRB approval from each individual institution, each with its own requirements of specific language, details in specific needs, etc., that hamper the initiation of the overall study."

In response to feedback from institutions with concerns about potential increased resources that may be required to modify business practices, update systems, and develop other tools needed to facilitate single IRB review,

NIH Implements Clinical Trials Policy Reforms *(Continued from page 5)*

the NIH also recently published a [Notice of Availability of Administrative Supplements for CTSA Awardees: Development of Resources to Facilitate Single IRB Review for Multi-Site Research](#). These awards aim to provide CTSA awardees with funds to help support institutional capacity building for the successful implementation of the single IRB policy. CTSA institutions have expertise in developing best practices and processes of single IRB review and have already developed resources such as the [NCATS SMART IRB platform](#) to support such review.

The Single IRB Program is facilitated by the SMART IRB Program, which has over 368 participating institutions, including all the institutions that have a CTSA. It is important to recognize that a study does not have to be funded by the NIH for an investigator or an institution without its own IRB to be able to use the SMART IRB Program. The SMART IRB program has IRB ambassadors who can help facilitate and guide an individual investigator.

The NIH has funded seven administrative supplements that provide one year of support for infrastructure and resource development in order to facilitate single IRB review. The awardees will develop resources for the broader research community and then share that information widely with other institutions. Awardees will share successful strategies and lessons learned for modifying and enhancing IRB infrastructure at a meeting in Washington, D.C., next year. These best practices will also be posted on the NIH website to help guide other institutions towards successful implementation of single IRB review. [Click here to learn more about the single-IRB policy](#).

[Click here for more information on NIH's New Clinical Trials Requirements](#) ■

NIEHS

NIEHS Releases Draft Strategic Plan

The NIH's National Institute of Environmental Health Sciences (NIEHS) has released its draft new Strategic Plan 2018-2023: Advancing Environmental Health Science,

Improving Health 2.0, for stakeholder comment. In her Director's Message about the plan, NIEHS Director Linda Birnbaum, Ph.D., says, "Our challenge was this: to set our research priorities within a rapidly evolving scientific landscape while ensuring that our science continues to be responsive to meeting the environmental health needs of people in the United States and around the world." The draft plan, which was developed following community comment in summer 2017, is composed of the following strategic objectives and corresponding focus areas:

1. Advancing Environmental Health Sciences

- Basic biological research
- Individual susceptibility
- The microbiome
- The exposome
- Co-exposures
- Predictive Toxicology
- Data Science and Big Data

2. Promoting the Translation of Data to Knowledge to Action

- Data to Knowledge
- Outreach, Communications and Engagement
- Evidence-based Prevention and Intervention
- Environmental Health Disparities/Environmental Justice
- Emerging Environmental Health Issues
- Partnerships for Action

3. Enhancing Scientific Stewardship, Infrastructure, and Support

- The Environmental Health Sciences Professional Pipeline
- Greater Workforce Diversity
- Promotion of Collaborative Science
- Training and Capacity-Building in Global Health
- Rigor and Reproducibility

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NIEHS Releases Draft Strategic Plan *(Continued from page 6)*

The full NIEHS draft strategic plan and narrative is on the [NIEHS website](#). Comments on the plan are due to the institute, through [an online survey](#), by March 30, 2018. The ATS will be submitting comments on the NIEHS strategic plan. ■

PATIENT ADVOCACY

PAR Profile – Allergy and Asthma Network

by Tonya A. Winders, President and CEO, Allergy & Asthma Network

The Allergy & Asthma Network is a leading patient advocacy organization aiming to raise public awareness and educate lawmakers about the importance of smart and effective policies and programs to end the needless death and suffering for millions of Americans living with asthma, allergies, and related conditions.

Principal issues in our advocacy efforts include sustained funding for allergy and asthma research and workforce development programs (e.g., graduate medical education). Our work to advance research opportunities and increase patient engagement leads to innovations in medical treatments. Continued work by the scientific and medical research communities, and funding of federal programs through the U.S. Centers for Disease Control and Prevention, Environmental Protection Agency, NIH, and GME, improves patients' health outcomes and quality of life.

Together with patients, families, health care professionals, and industry partners, we achieve our advocacy goals by amplifying the patient voice and forging connections in Washington, D.C., and communities around the country. We engage in federal and state policies and regulatory matters that impact communities of scientists, researchers, and educators while supporting patients.

Every May, we host Allergy & Asthma Day Capitol Hill in Washington, D.C., to raise awareness and address health care policy with federal lawmakers and staff. This event, now in its 21st year, gives patients and families the

opportunity to meet with federal legislators and discuss key policy issues, including health and research programs and workforce development. We also maintain an effective working relationship with the Congressional Asthma & Allergy Caucus, allowing us to advance policies that are patient-centered.

We value collaborating with other health care advocates and organizations. As a member of the American Thoracic Society's Public Advisory Roundtable, we advocate on behalf of patients and health care providers by speaking at Congressional and regulatory briefings, participating in coalitions with the American Lung Association and others, writing letters of support, and expressing concerns over detrimental policies.

We are currently advocating for the School-Based Respiratory Health Management Act (H.R. 2285). This federal legislation would ensure that school nurses, staff, and administrators are prepared to help students with reversible lower airway disorders, such as asthma, excel at school in a safe environment. The two most important strategies for preparing schools in the event of a lower-respiratory incident are implementing management plans and ensuring school staff members are prepared to assist children experiencing an attack. This act would encourage states to implement these changes so schools are better equipped to help students with asthma manage their disease. Currently, 12 states have laws or guidelines that permit schools to stock albuterol and to administer aid to a student believed to be in respiratory distress. ■

RARE DISEASES

NIH Rare Disease Day – March 1, 2018

On March 1, 2018, the NIH will host an event to raise awareness about rare diseases, the people they affect, and current research collaborations. Sponsored by the National Center for Advancing Translational Sciences (NCATS) and the NIH Clinical Center, Rare Disease Day will take place from 8:30 a.m. to 4 p.m. in Masur Auditorium

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NIH Rare Disease Day *(Continued from page 7)*

on the NIH main campus in Bethesda, Maryland. The event is free and open to the public and will feature presentations; interactive panel discussions on gene editing, gene therapy, and research collaborations; exhibits; and tours of the NIH Clinical Center.

Prior to the Rare Disease Day event, on Feb. 23, 2018, the NIH will host a Twitter chat on rare diseases from 1 to 2 p.m. ET. The chat will feature NIH Director Francis S. Collins, MD, PhD, and NCATS Director Christopher P. Austin, MD, as well as representatives from the rare diseases advocacy community. Join in the conversation via #NIHChat. You can learn more about NCATS's work in rare disease in the institute's Feb. 1 [Director's Message](#).

View the Rare Disease Day [agenda here](#) and [register for the event here](#). The event will be webcast. Follow the NIH Rare Disease Day on social media using #RDDNIH. ■

TOBACCO

California Tobacco Taxes Fund Tobacco Research

As one of three state agencies that work together towards the vision of a tobacco-free California, the Tobacco-Related Disease Research Program (TRDRP) aims to reduce the human and economic costs of tobacco use through innovative research and information dissemination. TRDRP works with the California Department of Public Health and Department of Education under the guidance of the Tobacco Education and Research Oversight Committee to ensure collaboration across all sectors of [California's tobacco control community](#).

TRDRP, solely funded through the state tobacco tax and individual contributions, supports critically needed new priorities that represent gaps in funding by other agencies or are areas where other agencies are reluctant or unable to provide support. Since the program's inception, it has funded more than 1,200 research grants on tobacco-related studies, with 95 percent of revenue going directly to funding research and education efforts. TRDRP revenue

is used to provide grants for California scientists and community researchers to find better ways to prevent and reduce tobacco use and its related diseases.

The TRDRP program began in 1988 when California voters approved [Proposition 99](#), The Tobacco Tax and Health Protection Act, which instituted a 25 cent per pack cigarette surtax. Five cents of each dollar collected supports critical tobacco-related research.

In 2016, California voters approved [Proposition 56](#), The Tobacco Tax Increase Initiative, which increased the cigarette surtax by two dollars with equivalent increases on other tobacco products and electronic cigarettes. Prior to passage of Prop. 56, the amount and duration of TRDRP awards had declined due to a decline in tobacco tax revenue. With passage of the proposition, TRDRP is now able to increase award levels and years of funding for all research award types. This has resulted in a substantial increase in funds available for research. Revenue from the cigarette tax will be allocated to physician training; prevention and treatment of dental diseases; Medi-Cal, tobacco-use prevention; research into cancer, heart, and lung diseases, and other tobacco-related diseases; and school programs focusing on tobacco-use prevention and reduction.

Research being funded by the TRDRP includes the following areas:

- Cross-cutting emphasis on research to reduce health disparities
- Expanded cancer research priority, including cancer prevention
- New expanded research focus in lung, cerebrovascular, and oral disease
- Cannabis use and tobacco-related diseases
- New award types to expand the research pipeline from high school students to independent investigators.

TRDRP is administered by the [Research Grants Program Office](#) at the [University of California, Office of the President](#). For information on applying for TRDRP grants, visit the [Applications page](#). ■

RESEARCH FUNDING

President Trump Releases 2019 Budget Proposing \$1 Billion NIH Cut

On Feb. 12, 2018, President Trump released his proposed budget for fiscal year (FY) 2019. The President's budget proposal includes some steep funding reductions in health and environmental programs. The budget also proposes significant changes to the Medicare and Medicaid programs that, if enacted, would have significant impact on program funding.

It's complicated

The President's proposed budget for FY2019 is confusing for several unique reasons, including a) FY18 spending bills aren't complete so we don't have a 2018 baseline to compare 2019 proposed spending, b) The President's budget was written before the February 9 budget deal so his budget is based on a \$63 billion lower spending cap than the actual cap, and c) the President's budget attempts to allocate the additional \$63 billion with an addendum that show how the additional money will be spent.

Needless to say, this is an unprecedented budget format. With that caveat in mind, we can say with confidence that this is how the following agencies important to ATS members and the respiratory community would fare under the President's budget:

- NIH – proposed \$1 billion cut
- CDC – proposed \$1 billion cut
- EPA – proposed \$6.1 billion cut
- AHRQ – proposal to move AHRQ to the NIH to become the National Institute for Research on Safety and Quality and a \$41 million cut
- VA Research – potential small funding increase (compared to FY17 levels)
- USAID global TB program – proposed \$63 million cut

Proposed Elimination of CDC's Tobacco Control Program

The President's budget proposes to completely eliminate the CDC's tobacco control program, the Office of Smoking and Health, which was funded at \$205 million in FY2017 and provides grants to states for tobacco cessation and education programs. The budget states that tobacco control would be administered by a new America's Health block grant, funded at \$500 million, which states would use to fund tobacco and other chronic disease and prevention research programs including obesity, heart disease and diabetes.

Other CDC Programs:

Under the budget, the National Institute of Occupational Safety and Health (NIOSH) would be moved to NIH along with a funding reduction of almost 25% or \$80 million

- Asthma – proposed \$3 million cut
- Tuberculosis – flat funding at the FY2017 level

Context

Republican and Democratic leaders on the Hill received the President's budget with little enthusiasm. In normal times, the party of the President uses the administration's budget as a starting point for budget development. It's fair to assume that party leaders on both sides will dismiss the budget and move forward to develop their own funding recommendations. The reality is that while a proposed \$1 billion funding cut for NIH is a very disappointing step by the administration, Congress will reject this funding reduction just as it rejected the President's proposed 19 percent cut to NIH in FY2018. Similarly, we expect that agencies like the EPA and CDC will not see the high levels of cuts proposed by the administration. ■