American Thoracic Society

Research News Quarterly

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In This Issue

Letter from the Editor

The February Research News Quarterly features an interview with National Heart, Lung and Blood (NHLBI) Institute Director Gary Gibbons, MD, where he reflects on the Institute's biggest achievements and challenges since his last interview with the Quarterly in 2012. Dr. Gibbons also outlines the main areas in the NHLBI's strategic research priorities that are particularly important for the respiratory community and other key questions.

This edition of the Quarterly also includes a feature on the National Institute of Allergy and Infectious Diseases' (NIAID) Asthma and Allergic Diseases Cooperative Research Centers (AADCRC), which support centers integrating clinical and basic research on the mechanisms underlying the onset and progression of diseases, including asthma, rhinitis and chronic rhinosinusitis. We include overviews of each of the 11 program centers, followed by an update on the release of the final NIH "Common Rule," which is making significant modernizing changes to human research subject protections. Next we give you the latest from the Precision Medicine Initiative and an announcement about upcoming Rare Disease Day events at NIH.

Moving to research policy developments, we have reports from our Washington office on the new 21st Century Cures law, enacted in Dec. 2016, and the outlook for health research funding for the remainder of 2017 and into 2018.

Sincerely,

Linda Nici, MD
Editor

INTERVIEW WITH NHLBI Director Gary Gibbons, MD

Q: We last interviewed you in Oct. of 2012 at the beginning of your tenure as director of the NHLBI. Can you reflect for us on what you see as some of the Institute's greatest accomplishments and biggest challenges since that time?

A: Our major challenge is to continue pursuing the best scientific opportunities in the face of limited resources. It is a balancing act that requires fostering innovation, maintaining the scientific workforce, and translating discoveries into better, more personalized approaches to prevent and treat disease.

I am a firm believer in the value of investigator-initiated science—including fundamental studies of biological systems in health and disease—for driving innovation in heart, lung, blood, and sleep research. For many years before I came to NHLBI, the success rate for research project grant (R01) applications had been on a steady decline. In FY 2012, it dipped to 14.7 percent among applications that received a percentile score. As an Institute, we made a commitment to reverse that trend, and each year, our R01 success rates have climbed higher, reaching 22.7 percent last year.

Maintaining a diverse and talented scientific workforce in heart, lung, blood, and sleep research requires attracting new scientists to the field, and nurturing their career development so that they can transition to independence. Guided by a strategic approach to funding, we have been able to expand our support for scientists at all stages of their careers. For example, our percentiled success rates for R01 awards to early-stage investigators increased from 19.7 percent in 2012 to 31.7 percent last year. Over the same period, our percentiled success rates for career development (K) awards increased from 27.7 percent to 41.2 percent.

In partnership with the rest of NIH, ATS, and other research funding bodies, our continued investments in science are moving us into an era of precision medicine when we will be able to tailor prevention and treatment to each person's unique biology and environment. However, much work remains to understand the risk factors and molecular pathways that contribute to chronic lung diseases. To that end, NHLBI's Trans-Omics for Precision Medicine (TOPMed) program is supporting whole-genome analysis of more than 70,000 diverse participants in existing NHLBI-funded studies. By combining genomic data with environmental, clinical, and imaging data, TOPMed will explore the

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Gary Gibbons Interview *(Continued from page 2)*

earliest points of transition from health to disease. For lung disease, the current focus is on asthma, COPD, idiopathic pulmonary fibrosis, and sleep-disordered breathing. These efforts are expected to reveal genetic and environmental risk factors for disease, as well as gene-environment interactions that could serve as new targets for intervention.

Q: Can you discuss key areas in the Strategic Vision that are particularly important for lung, critical illness and sleep?

During the Strategic Visioning process, more than 4,000 people—including basic and clinical scientists, patient advocates, and policymakers—answered our call for the NHLBI community to help shape our research priorities for the next 5-10 years. Those priorities will continue to evolve with scientific progress and community input. At this time, the NHLBI Division of Lung Diseases plans to enhance its focus in four major areas in the Strategic Vision:

- Development of **primary prevention** strategies to achieve optimal lung health and to help prevent the establishment of disease before symptoms manifest clinically.
- Encouragement of studies to understand variations in biology and response to therapiesin order to facilitate **personalized and precise interventions**.
- Development of multidisciplinary implementation research teams to accelerate the translation of evidence-based successful clinical interventions into practice.
- Development of tools and knowledge related to lung progenitor cells to enable **lung repair and regeneration** for treatment of lung diseases.

Q: Lung diseases continue to grow in prevalence and in health care expenditures. As director of the NHLBI, can you discuss some specific initiatives that you believe are addressing this growing burden of disease?

A: COPD is the third leading cause of death in the U.S. Recognizing the need for a coordinated effort to reduce morbidity and mortality from the disease, NHLBI has been working with our federal partners, patient advocacy groups, and other non-governmental organizations to develop a COPD National Action Plan. Early in 2016, we convened a COPD Town Hall at which more than 200 attendees—including patients, caregivers, health professionals, industry, academic leaders, and federal agency representatives—helped lay the groundwork. We released the plan for public comment in Sept. 2016 and expect to finalize it early this year.

COPD is heterogeneous and may exist as many genetically definable subtypes with distinct treatment needs. Ultimately, we hope to tailor the prevention, treatment, and management of COPD to each patient, ideally based on a reliable set of risk factors and biomarkers. Toward that end, the TOPMed program is supporting analyses of genomic, metabolic, clinical, and environmental data from people with COPD. Currently, the program supports whole-genome sequencing of nearly 15,000 individuals with COPD for whom lung CT scans are also available. Our hope is that TOPMed will yield new insights into the combination of factors that cause COPD and thereby suggest new, personalized approaches to therapy.

Asthma is another high-burden lung disease, particularly for African American children, who are twice as likely to have asthma as white children, more likely to be hospitalized for exacerbations, and more likely to die from asthma. We recently launched an initiative to support the development of Asthma Care Implementation Programs (ACIPs) that will address these disparities. In the first phase, nine research teams have completed community needs assessments to inform ACIP development. The next phase will support clinical trials to evaluate eligible ACIPs. We expect to fund these trials in summer 2017. We are also addressing risk factors for asthma pathology and outcomes through TOPMed, with whole genome sequencing planned for more than 31,000 individuals,

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Gary Gibbons Interview *(Continued from page 3)*

including people of African American, Puerto Rican, and Mexican ancestry.

Q: In the last Quarterly interview, we talked about some of NHLBI's translational research programs. Can you give us an update on those programs and discuss your vision for the future of translational research?

A: My vision for NHLBI's translational programs in lung research is to expand the armamentarium of effective therapies for chronic lung diseases. That includes identification of new targets for therapy, preclinical therapeutic development, first-in-human studies, and pilot trials in patients. We have a number of mechanisms to support these early phases of translation (T1-T2).

For example, we initiated our Centers for Advanced Diagnostics and Experimental Therapeutics (CADET) because many traditionally used therapies for lung disease (e.g., corticosteroids) lack specificity for the underlying disease pathology. The first phase of CADET supported research is to identify new, more precise molecular targets for therapy, and the second phase is supporting development of target-directed therapies. To date, the supported projects have focused on COPD, idiopathic pulmonary fibrosis, asthma, pulmonary hypertension, and sleep-disordered breathing. We also have a number of programs that provide regulatory support, clinical grade manufacturing services, and pharmacology/toxicology testing. Those programs include the NHLBI Gene Therapy Resource Program and the SMARTT program for development of small-molecule and biologic therapies.

Another high-priority for NHLBI is to support late translation and implementation science – in other words, efforts to move new health care tools and interventions into practice to improve public health (T3-T4). That's why we established the Center for Translational Research and Implementation Science (CTRIS). CTRIS works closely with our extramural divisions to identify gaps and opportunities in translation, disseminate new research findings, and inform the development of new clinical practice guidelines. It plays a lead role in addressing social, cultural, and economic barriers to the adoption of evidence-based interventions, which are a significant factor in health disparities affecting women, minorities, and people living in poverty.

Q: There is a lot of uncertainty in the medical and scientific communities about medical research and training? Can you provide an update on NHLBI efforts to support training and career development?

A: One of NHLBI's top priorities is to nurture a next generation of scientists prepared to address emerging opportunities in lung research. To that end, we've developed a number of strategies to support early-stage investigators with diverse backgrounds and expertise, and to help them make a faster transition to independent research careers.

For example, in FY 2016, we launched a unique Emerging Investigator Award (R35) mechanism that supports a research program, rather than a single project, to help turn early-stage investigators into scientific leaders. This seven-year award is intended to reduce the administrative burden of multiple grant submissions and to provide a nimble platform for supporting high-risk/high-reward research.

In addition to the R35 program, NHLBI also recently launched a pilot to increase success among early-investigators applying for research project grant awards (R01 or equivalent). Under this program, former and current recipients of certain K awards are eligible for small grants to extend or expand their current research, and thus strengthen their R01 applications. By helping young investigators cross this pivotal threshold, we hope to foster their transition toward independent research.

Q: Whe 21st Century Cures Act was recently signed into law. What are the implications of this law for the NHLBI and lung, critical care and sleep research?

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Gary Gibbons Interview *(Continued from page 4)*

A: The 21st Century Cures Act includes a wide range of provisions that will affect NHLBI, including a focus on opportunities for new and early-stage investigators. The law also places an emphasis on improving research related to sexual and gender minority populations, and ensuring that women, children, and minorities are appropriately represented in clinical research.

The Act also authorizes $4.8 billion over 10 years for an Innovation Fund for three ongoing initiatives: The Precision Medicine Initiative (PMI), the Brain Research through Advancing Innovative Neurotechnologies or BRAIN Initiative, and the Beau Biden Cancer Moonshot. It also authorizes $30 million over the next four years "for clinical research to further the field of regenerative medicine using adult stem cells."

The PMI cohort, recently renamed the All of Us research program, will enroll one million volunteers to enable research on genetic and environmental factors influencing a broad range of diseases. The All of Us cohort will provide opportunities for research relevant to lung disease and will be complementary to efforts of the TOPMed program to probe complex and challenging questions in lung disease research. ■

NIH

Collins to Remain as NIH Director for Now

National Institutes of Health (NIH) Director Francis Collins, MD, PhD, is to remain as director of the institute for the time being until a new director has been appointed. Dr. Collins submitted his letter of resignation, as is required during presidential transitions, but the letter was returned, indicating that President Trump wants him to remain as NIH Director. Dr. Collins's office reported that they had no additional information at this time. Dr. Collins, who has said he would like to continue as NIH director, met with President Trump last week.

Additional names that have been discussed as vying for the NIH Director post are biotech billionaire Patrick Soon-Shiong, MD and Rep. Andy Harris (R-MD). ■

NIAD

Update on the NIAID Asthma & Allergic Diseases Cooperative Research Centers & Associated Program Project Grants

The AADCRC program, the oldest NIAID program in asthma and allergy, has been a flagship research initiative for NIAID since 1971. The program supports centers that integrate clinical and basic research to conduct studies on the mechanisms underlying the onset and progression of diseases of interest including asthma, rhinitis, chronic rhinosinusitis, atopic dermatitis, food allergy, and drug allergy. The overarching goal of the program is to improve the understanding of the pathogenesis of these conditions and to provide a rational foundation for new, effective treatments and prevention strategies. The AADCRC program includes an Opportunity Fund that supports projects by junior investigators, as well as within AADCRC collaborative projects. In addition to the AADCRC, NIAID funds a number of asthma and upper airway disease Program Project Grants. AADCRC and Program Project investigators meet once a year to exchange their research findings. The following is a listing of the current AADCR's:

UCSF

The UCSF AADCRC grant examines the dynamic interactions between immune cells that produce IL-13 and IL-17 and the intrinsic lung cells whose dysfunction leads to clinical features of asthma. The program includes projects focusing on

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Update on NIAD and AADCRC *(Continued from page 5)*

- how IL-13 and IL-17 regulate airway epithelial cell differentiation and mucus production
- direct effects of these cytokines on airway smooth muscle
- the dynamic spatial relationships among cytokine-producing immune cells, epithelial cells and smooth muscle cells in the airways of mice sensitized and challenged with antigens
- people with asthma before and after direct airway challenge with relevant allergens.

University of California San Diego

The goal of this program is to challenge the current paradigm that asthma is a disease of airway inflammation which induces structural changes in the airway by proposing that asthma is a disease of both lung structural cells (smooth muscle) as well as airway inflammation (in particular, controlled by T cells and ILC2) and that developing therapeutic strategies to target both airway structural cells and immune/inflammatory cells is needed to control severe asthma with airway remodeling. In this regard, atopic dermatitis, is a good example of a disease that is part of the atopic march to asthma which is characterized not only by skin inflammation, but also by a genetic defect in a skin structural gene called filaggrin in a subset of people.

Stanford University

The major goals of the program are to conduct a large placebo-controlled, randomized, phase 2 clinical trial of oral immunotherapy (OIT) in children and adults with severe peanut allergy and to determine how immune system parameters change during OIT and which are most predictive of the nature and durability of responses to OIT. We also are trying to define the immune mechanisms underlying allergen-specific desensitization or tolerance in OIT and to identify immune parameters that can be performed in a clinical laboratory to predict the clinical reactivity to peanut in such patients in order to improve the safety and efficacy of OIT protocols.

Brigham and Women's Hospital, MA

This program focuses on the mechanistic basis of aspirin-exacerbated respiratory disease (AERD), a distinctive clinical syndrome that accounts for a disproportionate percentage of individuals with severe asthma and recurrent nasal polyps. Three projects are supported by Cores for Adminstration (Core A), Genomics/Informatics/Statistics (Core B), and Sample Biorepository and Analysis (Core C). The investigative team applies cellular, molecular, transcriptomic and network building approaches in humans with a novel mouse model and a proof-of-concept clinical trial to determine the mechanistic basis of the disease.

University of Wisconsin

Rhinovirus (RV) is an important cause of lower respiratory illness in children and exacerbations of asthma. The University of Wisconsin AADCRC Program consists of three interrelated projects focusing on host-RV interactions. The Wisconsin Infant Immune & Illness Surveillance Cohort ("WISC") will define how farm exposures in early childhood enhance antiviral responses, and reduce morbidity from viral respiratory illnesses. Project II is using molecular approaches to define the biochemistry and 2A protease of the newly described RV-C species. Finally, in Project III researchers are investigating how RV replication in single cells stimulates immune responses and defining mechanisms of spread to neighboring cells. Collectively, these three projects will identify new targets for the treatment and prevention of HRV infections.

Vanderbilt University Medical Center, TN

RSV is the leading cause of bronchiolitis and results in greater than 100,000 infant hospitalizations in the U.S. each year. Studies have also revealed that severe RSV infection in infancy is associated with the later development of childhood asthma. In project one, 1,950 children in Middle Tennessee were enrolled in the first funding cycle and will be followed in the next funding cycle to determine the influence of RSV strains on both host genetic and immune response determinants on severity of RSV bronchiolitis and childhood asthma. In project two, we will determine the specific effect of this mutation on disease severity in mice so that we can better understand the mechanisms by which this mutation causes increased illness in humans.

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Update on NIAD and AADCRC *(Continued from page 6)*

University of Cincinnati

Allergic disorders are a global health concern. Recently, epithelial cells have emerged as central participants in the pathogenesis of allergic inflammation. Defining the key epithelial drivers of the development, persistence, and progression of allergic inflammation is the focus of this application. Through the synergistic projects, these projects will provide novel insights into a key unanswered question in the allergy field: Why is allergic inflammation restricted to one tissue in some cases, while it progresses to involve additional tissues in other individuals? Investigations in this domain will ultimately provide a road map for primary or secondary prevention of allergic disease.

Benaroya Research Institute

This program's hypothesis is that the airway epithelium is the central coordinator of responses to respiratory virus infection, as well as to allergens. Airway epithelial cells (AEC) from asthmatics respond in a different manner to infection than do AECs from healthy patients. These differences are manifested during infection in several ways, including changes in the expression and deposition of extra cellular matrix components and qualitative and quantitative differences in the expression of cytokines and chemokines. The primary goal of this program is to identify and characterize these changes in asthmatic AECs and determine their effects on the innate and adaptive immune response. The studies in this Center are designed to determine the role of the airway epithelium in virus-induced exacerbation to gain insights into new pathways that may yield new therapeutic targets.

This program also supports the following three P01 grants in allergic disease/severe asthma:

CRISP Consortium

CRISP is composed of investigators at Northwestern University, University of Chicago, Geisinger Health Systems and Johns Hopkins University. The main goal of this program is to significantly advance our understanding of the immunology, epidemiology and genetics of chronic rhinosinusitis (CRS). Investigators are focusing on pathogenic mechanisms of disease, defining phenotypes of disease, performing a large evaluation of epidemiology in a primary care population and using a systems genetics approach to identify important genetic and environmental influences on disease. The CRISP program also has a strong goal of training next generation investigators in CRS.

Henry Ford Health System"

This program project includes Henry Ford Health System, University of Michigan, UCSF and Augusta University. The research is designed to gain an understanding of the extent and mechanisms through which the initial gut microbiota of children influences their risk of asthma and allergic disease. Studies are based on multiple interactions between epidemiologic research of two birth cohorts and detailed examination of bacterial and fungal community development, associated metabolites and immune development in children. Ongoing work seeks to relate the findings in the first few years of life to allergic asthma at 10 years of age and a better understanding of how bacterial metabolites influence immune development.

University of Pittsburgh

Unlike mild asthma, severe asthma is poorly managed by the current standard of care, which results in frequent (and high cost) exacerbations, poor disease-associated quality of life and high long-term risk for side effects of corticosteroids (CS). The key hypothesis that will be tested in the program at the University of Pittsburgh is that the immune mechanisms underlying CS-refractory asthma are distinct from those induced in milder disease, which differentially impact the airway epithelium. The study will employ CyTOF to determine the immune fingerprint of the airways and peripheral blood of individual subjects with mild or severe disease. RNA-seq of cells in bronchoalveolar lavage fluid, peripheral blood and the airways will be analyzed by cutting-edge bioinformatic tools. Integration of clinical, immunological and molecular data will allow us to more comprehensively define the complexity and heterogeneity of asthma potentially identifying novel targets for more effective therapeutic intervention.

NIH Issues Final Common Rule Changes

In January 2017, the Department of Health and Human Services released the final rule to modernize the Common Rule governing human research protections. The finalization of the rule was the result of an effort to improve the Common Rule regulations that began several years earlier, in 2011. The final rule aims to strengthen protections for patients involved in studies while simultaneously reducing administrative burdens for researchers. Most requirements of the rule will go into effect in 2018.

Several ATS committees reviewed and drafted comments on the previous iterations of the rule including the Research Advocacy Committee, Drug, Device Discovery and Development committee, Quality Improvement and the Scientific Advisory committee.

ATS Research Advocacy Committee chair Linda Nici, MD, said, "The ATS supports the recently released final rule to update regulations designed to safeguard research participants, known as the Common Rule. We are delighted that significant changes were made to the first draft in response to public comment, including that of the ATS." Specifically, the committee is pleased to see the following changes in the final rule:

- Increased transparency and streamlining of the consent process so that investigator burden is minimized and patients can make a more fully informed decision
- Flexibility in the use of a single IRB for multi-institutional studies, with a modification from the proposed rule to permit broader groups of studies to be exempt from this requirement
- Broad consent for future research studies without having to obtain consent on non-identified data or biospecimens. The final rule does require patient consent forms for certain clinical trials to be posted on a public NIH website.
- Revisions of the risk-based framework to allow for appropriate exemptions for low risk studies
- Ending continuing review requirements for some studies where it is determined that additional review will not benefit research participants.

Other changes include:

- The final rule does not require new standardized privacy mechanisms as proposed under the previous rule and instead maintains current privacy requirements.
- The final rule does not extend the Common Rule to clinical trials that are not federally-funded, as was proposed under the previous rule.
- The final rule does not adopt some of the tools and standards such as a template for broad consent forms and a decision tool for making exemption determinations that were proposed under the first rule. ■

NIEHS

NIEHS 50th Anniversary

On Nov. 16, 2016, through its leadership of the Friends of the National Institute for Environmental Health Sciences, the ATS convened a briefing and honorary reception to commemorate the Institute's 50th anniversary on Capitol Hill. ■

From right to left: ATS member Joel Kaufman, MD, professor of environmental and occupational health sciences, University of Washington; Virginia Rauh, ScD, professor of population and family health, Columbia University, Linda Birnbaum, PhD, director, NIEHS; Robert Wright, MD, MPH, professor of environmental medicine and public health and director, Mount Sinai; and Sarah Ervin, Honest Co.

PRECISION MEDICINE

NIH Launches All of Us Research Program

In 2015, President Obama launched the Precision Medicine Initiative® (PMI), aimed at fostering collaboration with researchers, health care providers, and patients to develop individualized patient care through advances in research, technology, and patient empowerment. The PMI's research cohort, called the All of Us Research Program, is seeking one million or more patient participants nationally who are willing to share their health data and information for the next 10 years in order to facilitate greater understanding of the factors contributing to individual health and disease. Specifically, All of Us is intended to:

- Develop ways to measure risk for a range of diseases based on environmental exposures, genetic factors, and interactions between the two;
- Identify the causes of individual differences in response to commonly used medications; and,
- Discover biological markers that signal increased or decreased risk of developing common diseases.

One of the areas that will set the program apart is its diversity, specifically its commitment to "quadruple diversity," defined as diversity in terms of people (people of all ages, races and ethnicities, sexual orientations, and socioeconomic statuses), health status, data types, and geography. All of Us will be doing intensive multicultural outreach in order to fulfill this commitment.

Participants will undergo a standard baseline exam for vital signs, medication assessment, and past medical history, and provide a blood sample. The Program will be a highly interactive research model where patient participants will have significant representation in the Program governance and oversight. Patient data will be protected by rigorous privacy and security safeguards. A key part of All of Us is early engagement with providers to help ensure that they have the information and tools they need. Enrollment for All of Us will begin later this year and NIH will widely publicize the enrollment period.

All of Us recently opened a funding opportunity for nonprofit and community-based organizations and local governments interested in volunteer recruitment for the program. Grant awards are up to $5 million annually for a three-year period to support community-led outreach efforts to complement the program's current efforts.

Applications are due on March 24, 2017, and NIH plans to issue awards in May 2017.

As discussed by Dr. Gibbons in his interview with the Quarterly, NHLBI's key PMI initiative is the Trans-Omics for Precision Medicine (TOPMed) program, which is collecting and analyzing whole-genome sequencing data from diverse-populations in currently NHLBI-funded studies, including patients with COPD. NHLBI has released the first whole TOPMed genome sequence data, which included almost 9,000 sequences. The sequencing data are available to researchers through the online Database of Genotypes and Phenotypes (dbGAP). New TOPMed data will be released about twice a year. ■

NIH Holds Rare Disease Day Event – February 27, 2017

The National Center for Advancing Translational Sciences (NCATS) and the NIH Clinical Center are sponsoring an all-day event for Rare Disease Day on Feb. 27 at the NIH campus in Bethesda, MD. Rare Disease Day takes place globally on the last day in February to raise awareness with the public and policymakers about rare diseases and their impact on patients' lives.

Rare Disease Day activies include NIH Clinical Center tours, posters, exhibits, art shows and presentations. Admission is free and open to the public in person or via webcast. Click here for more information and to register for the event. ■

RESEARCH POLICY UPDATES FROM WASHINGTON

Cures Research Bill Enacted into Law

Before adjourning for the end of its session, Congress approved a large health research package known as the 21st Century Cures Act (CURES Act), which President Obama the signed into law. The Senate passed the legislation by a bipartisan vote of 94 – 5, following passage by the House by a similar bipartisan vote of 392 - 26. The major intent of the law is to speed the discovery and FDA approval of new therapies and cures and $200 million in additional funding for the agency.

The original version of the legislation that passed the House of Representatives last summer included $8 billion in funding, some of which would have been applied across all NIH institutes, but in Senate negotiations, the NIH funding was reduced and applied only to support to NIH's Precision Medicine Initiative, the Cancer Moonshot, BRAIN Initiative and regenerative medicine research. The law encompassed other health-related provisions, including mental health legislation and measures to address opioid addiction.

The ATS worked with bill sponsors and congressional committees to ensure provisions of the PATH Act were included in the CURES bill. The PATH Act creates a new FDA approval pathway for new antibiotics for drug resistant infections such as pneumonia, sepsis and tuberculosis. To build broad based congressional support for the bill, the ATS dedicated our ATS Hill Day in 2015 and 2016 to increasing support in Congress for the legislation. The ATS's efforts were also successful in getting initiatives for young investigators and pediatric research included in the final bill. Despite the efforts of the ATS and other research societies, the bill did not include dedicated funding for future NIH increases as part of the final legislation package. The law's main provisions of interest to ATS members are:

- $4.8 billion in funding for NIH's Precision Medicine Initiative, Cancer Moonshot, BRAIN Initiative and regenerative medicine research
- PATH Act – a measure to create a new expedited FDA approval pathway for new antibiotics with limited patient populations (a key request at ATS Hill Day 2016)
- Renewal of the FDA rare pediatric disease incentive program
- Renewal of the NIH's National Pediatric Research Network focused on rare diseases and birth defects
- Creation of an expedited approval pathway for breakthrough medical devices
- Initiatives for young investigators including creation of a new NIH office of Next Generation Researchers and increasing the NIH loan repayment award from $35,000 to $50,000
- Measures to reduce the administrative burden on researchers
- Improvements in the FDA and NIH scientists' ability to attend scientific conferences. ■

RESEARCH FUNDING

Trump Administration Budget

The current FY2017 spending measure funding government programs will expire on April 28, 2017. Congress and the administration must enact a spending measure to fund the government for the rest of the year by this date. The fiscal year 2018 spending process will begin when President Trump releases a proposed budget overview for fiscal year 2018 in early February. This budget proposal will outline department and major agency funding but will not provide proposed funding levels for individual programs. A full FY2018 budget proposal will be released in April, 2017. Proposed funding cuts to some programs that the ATS monitors, such as public health, global health and environmental health protection, are expected and member advocacy in support of research and public health programs will be needed. ■