American Thoracic Society

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In This Issue

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Letter from the Editor

The March Research News Quarterly continues our interview series with NIH and federal program heads with a conversation with the Assistant Administrator of the Environmental Protection Agency's Office of Research and Development Thomas Burke, PhD. In this interview, Dr. Burke outlines the program's focus to inform regulatory decision-making and protect public health and the environment through scientific research on the effects of climate change and air pollution.

Next we report on recent moves in Congress to limit scientific representation on federal advisory panels, followed by an update on the release of the NHLBI's new strategic research priorities. We also cover the NIH's final regulations making changes to the Common Rule on human subject research protections and the ATS's position on these revisions.

Funding boosts for the Veterans Administration and Department of Defense medical research programs are the subject of the next update, followed by an announcement on new child health research funding opportunities now available through the NIH's ECHO program. Moving to comparative effectiveness research, we have an article on the Patient-Centered Outcomes Research Institute's (PCORI) new lung research projects. The March Research News Quarterly is rounded out with an update from our Washington DC Office on how health research funding fares in the President's proposed budget for 2017.

Sincerely,

Linda Nici, MD
Editor

INTERVIEW WITH THOMAS BURKE, PhD

Assistant Administrator, Office of Research and Development, Environmental Protection Agency

Q. What is your vision for the EPA research program?

A: The clean air science community, led by organizations such as the American Thoracic Society, is squarely focused on the ultimate goal of "helping the world breathe." We share that goal. That is why my vision is to see the great work of dedicated scientists and engineers flowing to those who can use it to make positive differences in communities across the nation and around the world. We are embracing partnerships in ways that remove the barriers between the research community and nurses, physicians, and healthcare providers—those working tirelessly on the frontlines every day to improve the lives of people struggling with respiratory health issues. Our goal is to design our research in ways that help accelerate innovation and the proliferation of data in ways that match both the urgent and long-term needs of the public health community. I've worked as a public health official, as an academic researcher, and now as a federal official with the responsibility and privilege to lead EPA's Office of Research and Development, and I see how we can all work together. My vision is to see the clean air science community continue to make strides so that the every individual can benefit from our collective research.

And that vision is achievable. High quality science has already provided the foundation for all of EPA's achievements over the last 45 years. We are now advancing a highly integrated, interdisciplinary and efficient research portfolio focused on providing the answers we need to meet today's complex, far-reaching environmental and health challenges. And while that important work goes on, we also provide the scientific basis to inform major policy decisions and respond to emergencies. The goal is always the same: supporting and improving public health and the environment throughout the nation. A great example is our Air, Climate, and Energy Research Program, or ACE, which provides the essential and innovative science and engineering needed to address the challenges of protecting human health and the environment from the impacts of climate change and air pollution. These challenges are complicated by the

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interplay between air quality, the changing climate, and existing and emerging energy options.

Q. How does the ORD research program help inform EPA regulatory decision making?

Virtually every decision EPA makes is based on science. Our 45-year record of success in protecting public and environmental health from air pollution has relied on building a strong scientific foundation to inform policy decisions. Again, clean air is a great example. Today, improving the Nation's air quality remains a major EPA priority, especially for those who reside in communities unable to fully meet air pollution standards or who may be at increased risk for health or socio-demographic reasons. Even more pressing is the Agency priority to address climate change, which has significant negative implications for human health and the environment.

Ambient air pollution can have significant adverse consequences on human health and the environment. Inter-disciplinary research conducted and supported by EPA scientists has demonstrated that exposure to air pollution can cause a wide range of human health and environmental welfare effects. This science is incorporated into the Agency's Integrated Science Assessments and Integrated Risk and Information System assessments that serve as the scientific basis informing decisions for the national ambient air quality standards and hazardous air pollutant regulations, respectively. Research has informed and enabled the nation's efforts to curtail air pollution emissions and improve air quality dramatically since the establishment of EPA in 1970. While we have seen enormous public health and economic benefits, much work remains and new challenges are emerging.

Climate change is a major one. It is even beginning to roll back some of the air pollution achievements we have made in the past, and may be impacting human health and the environment in other, potentially serious ways. Climate change is leading to higher concentrations of some air pollutants and increasing stressors such as heat and allergens that may worsen respiratory systems and health outcomes. Simultaneously the presence of some air pollutants in the atmosphere is affecting the rate of climate change itself. The changing climate is causing an increasing range of major and adverse effects on air quality, water resources, agriculture, wildlife ecosystems, contaminated sites and waste management practices, as well as the built environment (i.e., energy, infrastructure, and communities).

Continued improvement in understanding of air pollutant emissions, atmospheric processes, exposure, and effects is critical to ensuring that we meet those challenges, and have the data and information we need to protect public health now and into the future.

Q. What type of research questions are you interested in addressing in particulate matter research?

Because of the health risks we know are associated with particulate matter exposure, it is a major focus of our clean air research. We are working to strengthen the review of the particulate standards, especially reducing the uncertainties and limitations that remain in linking ambient PM levels and observed health effects. In addition, we are closely examining the extent to which the heterogeneity observed in the epidemiological evidence is related to differences in the ambient particle mixture and/or exposure-related factors.

As national ambient concentrations of most pollutants, including particulate matter, decrease, disparities in exposure and risk emerge. Why need to know what's behind that so we can help everyone benefit from cleaner air. To do that, we are conducting critically important studies aimed at lower ambient concentrations and improving our understanding of those groups that are within the general population but at increased risk to health impacts.

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Beyond improving our understanding of the spatial and temporal variability of particle exposures, we need to understand particulate matter in real world scenarios. No one has the option of breathing in just a single class of air pollutant. So, are working to fully understanding the role of particulate matter in relationship to that of gaseous co-pollutants within complex ambient mixtures—all in the context of the changing climate.

On the health side, significant questions remain as to who comprises the most sensitive subpopulations, or the salient risk factors that may contribute to their responsiveness of sensitivities. Genetic, health status, and even exposure vulnerability—that is, environmental justice—factors are clearly involved but re not fully understood.

The ACE Team within EPA's ORD is seeking to better integrate and translate both the science that supports regulatory standards as well as to broaden the usefulness of this information for a wider range of stakeholders. We have ongoing research within ORD and through grant affiliates addressing the spectrum of questions noted above. We believe there is also a growing need to provide consumable information to individuals, communities, and regions to inform their personal decisions related to minimizing air pollution exposures.

Q. Human challenge studies have come under scrutiny from some policy makers. What role does EPA foresee for human challenge studies in EPA research portfolio?

EPA uses many different approaches in fulfilling its mission to protect public health. Controlled exposure studies fill an important gap between what can be learned from laboratory experiments, animal toxicology studies and observational studies in humans (i.e., looking at what the general public experiences from their routine environmental exposures). Controlled human exposure studies have historically been the foundation for the several of the NAAQS pollutants – ozone, CO, NO2, SO2 and to a lesser extent PM2.5. The human exposure studies coupled with animal toxicology studies have provided the "biologic plausibility" basis from which we can maximize the utility of epidemiology findings. As you know, epidemiology gives us evidence that pollutants have negative effects on human health, but we don't fully understand the biological mechanisms behind these health effects, or why some groups react differently. It is the controlled exposure studies that help us understand underlying mechanisms, which ultimately translates into improved prevention and treatment strategies.

In any controlled human exposure study, the safety of our research volunteers is paramount. We are committed to the highest safety and ethical standards for protecting our human studies volunteers while we work to advance the science needed to protect human health. To maintain such strict standards, EPA is among 17 federal agencies that have adopted rules governing the protection of human subjects in research. Beyond that, EPA's standards far exceed what is generally accepted and required by universities, industry, and other government agencies. For example, any of our research that involves human participants typically undergoes more than eight separate levels of approval before any research is initiated.

Exposure studies involving research volunteers are highly controlled. If there is the slightest concern that a proposed study or protocol will not meet the highest safety standards, it will not be carried out. Participants are carefully screened and informed consent is obtained. Precautions are taken throughout the volunteer's participation to ensure his or her safety. As a result, EPA has an excellent track record of safety in studies conducted over many decades.

Going forward, controlled human exposure studies will be used with the same cautious and judicious consideration of risk to the subject and value of the knowledge, with the health and safety of volunteers

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clearly the preeminent decision factor. As it is with the development of sophisticated statistical models for field epidemiology coupled with new sensitive biomarkers and other non-invasive bioassay tools, more emphasis of late is being placed on real world exposures in the living environment people experience day to day. Studies designed around these conditions are grounded in the knowledge we have gained over the years and related animal and in vitro studies empowering our translational abilities. But as the need arises, the juried used of controlled human exposure studies remains a valuable tool to air pollution health science.

Q. How have new air pollution monitoring techniques been incorporated into EPA research agenda?

This is one of the most exciting areas of our research and in clean air research in general. We are taking full advantage of new technologies and embracing innovation to lead the next-generation of clean air research and to protect individuals wherever they live and work. EPA researchers have been at the forefront of the recent revolution of new portable, low-cost air pollution sensors. Over the past 5 years we have convened workshops involving technology developers, interested community representatives and scientists, from within and outside the Agency, to help nurture this growing phenomenon. We have evaluated some sensors in laboratory and field tests and applied some of the more promising technologies in our own field studies.

An example is a sampling platform we have developed, the Village Green, which incorporates air pollution sensors into a park bench intended to be placed in community settings. The Village Green stations operate off solar and wind power to measure PM and ozone as well as important meteorological parameters all the while cellularly broadcasting the data where it can be reviewed for quality and eventually provided to the public via EPA's AirNow database. There are now 5 Village Green stations in cities across the U.S. including the original station in Durham, NC; Washington, DC; Philadelphia, PA; Hartford, CT; Houston, TX and another soon to be online in Chicago, IL. There's even one operating in Hong Kong. We recently hosted a training workshop in summer 2015 intended to prepare interested community scientists to use low-cost sensors to better understand local air pollution in their communities. We're also developing approaches where portable technologies can be used to understand emissions of air pollutants at the fence lines of industrial facilities.

Q. While all particulates have a health effect, recent studies have shown that particle pollution from some sources have more adverse health effects than from other sources. How will the EPA research program address the unique health effects of particles by source?

Studying air pollution sources is another area EPA has made a priority. The ACE research program is making a significant effort assessing emissions from a range of sources, focusing on the nature of the emission, measurement and control technologies, and in the evaluation of potential health outcomes. This health research effort may involve source apportionment links within epidemiological contexts and/or human or animal toxicological studies.

Although far from the only one, the major effort has been applied to near road and traffic related pollution. This work has been conducted both by our own staff researchers, and by other leaders in the field through EPA's grant structure.

Together, what we are learning is that the composite message is that a sizeable portion of the PM2.5 health impact seems to derive from traffic. While traffic often translates to interest in ultrafine particles, the health data linking to ultrafine particles remains unclear. It's a challenge to study. For example, the role of copollutants

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from vehicle emissions may play a role, but the co-correlation of the emissions makes it extremely difficult to sort the various contributing factors. While traffic in urban environments has this signal, particles derived as prime particles and as secondary particles (photochemically transformed from gases) also show health impacts. These impacts can be acute in outcomes (cardiovascular events) or may have chronic implications such as atherosclerosis or worsening of chronic lung disease.

At the same time, studies funded through EPA as well as by HEI have been unable to show clear component or physical attributes as primary drivers of health effects, which leaves PM mass—regardless of the sources—as yet the best indicator of health risk. Given that, we see we need to look at which sources are important on a local level. As background ambient PM levels continue to fall, the significance of specific or point sources of PM may come to light as local drivers of unique health outcomes, but to date this kind of linkage is not applied at the national ambient domain. Efforts to push down on emissions from vehicles – gas and diesel – are main targets of source control. Likewise, power plant and related stationary source emissions are also being targeted for reductions.

Health research is looking more into the multipollutant relationships, susceptibility factors, and the potential for interventions to mitigate outcomes while at the same time learning more about mechanism and how PM from sources function , perhaps through common pathways. As climate change interacts with air chemistry, there if growing concern that the nature of air pollution may change in such a manner as to alter outcomes or perhaps lose ground from earlier advances in health protection. When coupled with changes in human behavior and evolving exposure scenarios, the issues will call for truly innovative approaches to air pollution assessment, the weighing of source attribution, and problem resolution. ■

REGULATORY

Science, Process, Politics, and Regulation

Federal agencies responsible for protecting the public health and the environment have long relied on scientific evidence to both justify regulatory action as well as shape federal rules. From tobacco, to acid rain, to air pollution, and climate change and a host of regulations in between, research findings and the scientists who conduct the research, have played a pivotal role in both advocating for and guiding federal regulation. Over time, scientific findings have led to important public health and environmental regulations that have improved the health and well beings of Americans.

For several years, the ATS has played an active part in the regulation process. ATS actions have been guided by scientific evidence. The ATS has actively advocated for stronger air pollution and tobacco regulations. Noting the known adverse health effects of occupational exposures, the ATS has also called for more protective occupational standards for silica, beryllium, and coal dust exposures. While there is much work yet to be done, the ATS can proudly and accurately say it has played a constructive and important role in major public health regulations.

And for every action, there is a reaction. All of the regulations that were supported by science and advocated for by the ATS and sister organizations were forcefully opposed by the regulated industry. Through the regulatory comment process, through courts and through political pressure on Congress and the White House, impacted industries have sought to stop, weaken, or delay important public health regulations. While industry can certainly point to several “wins”

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Regulatory *(Continued from page 6)*

where they have delayed important rules, over time, the regulatory policy making process tends to most value input from the scientific community. When reviewing the legal authority and appropriateness of regulations, courts respect agency jurisdiction and scientific documentation over industry claims. In short, over time, the regulatory process is continuing to result in more protective standards that improve our nation's air quality. And this is why industry and their supporters are working hard to change the process.

Over the past few years, Congress has passed a series of bills that would change the regulatory process in ways that would reduce the role of science and scientists in the policy making process, give industry more process and legal tools to delay important legislation, and reduce the ability for independent federal agencies to promulgate regulations to protect public health.

The House of Representatives has already passed several bills, including the EPA Advisory Board Reform Act and the Secret Science Reform Act. Together these bills would reduce the ability of qualified scientists to participate in federal advisory boards, increase agency costs for promulgating federal rules, and add more legal and procedural tools for industry to block or delay important regulations.

The Senate is expected to consider a bipartisan set of regulatory reform bills that will significantly tip the scales in favor of the regulated industry. While details of the regulatory reform package are still being developed, it is likely to consist of an amalgam of existing regulatory reform bills. If enacted, these reform bills would change the regulation process by the following:

- Additional regulatory process steps requiring advanced notice of proposed rule-making into the required federal regulation process.
- Require additional costs benefit analysis, beyond the current cost benefit analysis already conducted by the administration.
- Create a cost/benefit review system that favors regulated industries.
- Require a review and report on all major federal regulations and prevent any regulations under consideration from being implemented until the report is complete.
- Allow a newly elected president the ability to strike any regulation that was released in the last six months of the previous president's term.

In sum, the reform bills seek to change the process by which regulations are made, increase industry leverage in the rule making process, and weaken and delay public health regulations.

While the reform bills would apply to a broad array of regulations, the first casualties of the regulatory reform efforts would likely be air pollution standard—ozone and particulate matter—and climate change rules that are of interest to the pulmonary community. ■

NEWS FROM NHLBI

NHLBI Releases Strategic Research Priorities

The NHLBI recently released its draft strategic research priorities document for public comment. The document is the product of NHLBI's internal strategic visioning process and public stakeholder participation process. The institute received over 1,200 ideas in the form of compelling questions and critical challenges in response to the strategic visioning framework document released February 2015. The ATS Research

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News from NHLBI *(Continued from page 7)*

Advocacy Committee is reviewing the document and preparing comments on behalf of the ATS.

The research priorities draft is organized broadly through four overall strategic goals and eight corresponding objectives that were outlined in the framework document. The strategic goals are:

1) Understand human biology;

2) Reduce human disease;

3) Advance translational science; and

4) Develop workforce and resources.

The 8 strategic objectives are:

- Biology
- Pathology of disease
- Health disparities among populations
- Identification of differences in disease pathology and response to treatments
- Development and optimal use of diagnostics and treatment tools
- Optimization of translational, clinical, and implementation research
- Data and analysis
- Workforce development

The third and most extensive part of the document is the final draft list of compelling questions and critical challenges, organized in alignment with the above goals and objectives. NHLBI accepted comments on the research priorities draft through March 7. The final NHLBI strategic research priorities should be out by summer 2016. View the NHLBI strategic research priorities draft and the overall strategic process here.

HUMAN RESEARCH PROTECTIONS

ATS Comments on Common Rule Changes

As we reported in the last Quarterly (Fall 2015), the NIH's Office of Human Research Protections released a proposed rule to modernize and strengthen the Common Rule governing human research protections. The proposed rule was the result of an effort to modernize and improve the Common Rule regulations that began in 2011, which have become even more important in light of the precision medicine initiative and movement towards personalized medicine.

The main comments provided by the ATS pertain to the following items:

- Improving and streamlining the informed consent process
- Revising the existing risk-based framework to more accurately calibrate the level of study review to the level of risk
- Further stratifying risk in scientific research studies and reduce administrative burden for lower risk studies
- Clarifying the informed consent process for use of stored biospecimens in secondary research
- Using single Institutional Review Board (IRB) review and unaffiliated IRB Common Rule Coverage
- Providing uniform guidance on federal regulations
- Clarifying the scope of the Common Rule to all clinical trials Conducted at U.S. institutions receiving federal funding

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Human Research Protections *(Continued from page 8)*

Several ATS committees reviewed and drafted comments on the rule on behalf of the ATS including the Research Advocacy Committee; Drug, Device Discovery and Development Committee; Quality Improvement Committee; and Scientific Advisory Committee. The committee members generally supported the changes outlined in the proposed rule and recommended that the OHRP reduce the overall number of consent forms and limit them to deal with each study's research protocols, rather than the full standard of care in a study. The ATS cautioned that there may be some unforeseen future risks that cannot be anticipated and investigators should not be retroactively held accountable in these situations. In addition, the ATS advocated for the creation of decision-aid tools including a website for patient participants to more easily access information on study risks and benefits.

The ATS supported a revision to the existing risk-based framework to more accurately calibrate the level of study review to the level of risk to patients, and to exclude low-risk research activities. Committee members felt that more accurate information about the level of risk for subject participants will better inform participants and increase efficient categorization of studies where those designated as minimal risk can be reviewed more expeditiously while the higher risk studies receive more time and attention. This would ultimately reduce administrative requirements for minimal risk studies and time delays for all studies.

The ATS also supported the proposed rule's modifications to the scope of research including the potential exclusion of some studies currently covered under the Common Rule. The ATS believes that studies such as those pertaining to quality assurance and improvement, and public health surveillance projects (many of which are covered by Health Insurance Portability and Accountability Act), would benefit from exempt status. This would reduce the administrative burden on investigators and patient subjects allowing for more timely progress of research. Likewise, the ATS supported the OHRP's proposal to eliminate the requirement for continuing review for studies that are granted expedited review and for studies that have completed study interventions and are analyzing data or conducting observational follow up as another means of reducing regulatory burden.

The ATS recommended increasing flexibility as well as clarification on the rule's proposal to require informed consent for future use of stored biospecimens. Given the significant planning and time needed for implementation of new tracking and processing systems, the ATS recommended that the requirements be phased in over time beyond the three years originally proposed in the rule. The ATS also expressed concern with the proposal to set a ten-year time limit on the future use of bispecimens and recommended that OHRP instead allow biospecimen use in secondary research in perpetuity. Committee members felt that with the exponential growth in our understanding of the genetic basis for disease, a ten-year window for informed consent of biospecimen use may be too short, causing delays and hampering future studies.

The ATS supported another significant change that was originally proposed in 2011, which is a single IRB review for multi-site studies, although the ATS recommended clarification on implementation of this goal. Specifically, the ATS requested clarification regarding whether a single set of federal guidelines will still apply, what governing body will define the rules, and how arbitration will be carried out.

Finally, the ATS expressed some concern to OHRP about the extension of federal regulations to all clinical trials whose institutions receive federal funding, in that this may lead to increases in administration and costs for institutions not formerly covered under the Common Rule.

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Human Research Protections *(Continued from page 9)*

The deadline for comments on the OHRP rule closed on Jan. 6. The office will now review all public comments and issue a final rule later this year. The final rule will complete the process for modernizing the human research subject protections and mandate the new changes for all research studies receiving funding from a federal government agency. ■

DOD RESEARCH

2016 Funding Increases for VA and DOD Research Programs

In addition to a funding increase for the National Institute of Health, the Fiscal Year 2016 omnibus spending bill included some more good news in the form of funding increases for respiratory research through the Department of Veteran's Affairs Medical and Prosthetic Research program and the Department of Defense's Peer Reviewed and Congressionally Directed Medical Research Programs (PRMRP) and (CDMRP).

The VA Research program received a 7 percent funding increase over Fiscal Year 2015 funding in the 2016 omnibus spending bill, putting funding at $630.7 million. The VA Research program funds discovery and innovation research on health issues affecting veterans, including respiratory diseases such as COPD and lung cancer.

The PRMRP program received a 12.5 percent funding increase in the 2016 spending bill, putting funding at $278 million. The program has also expanded its list of diseases eligible for research funding support to include pulmonary fibrosis (first included in 2015), acute lung injury, constrictive bronchiolitis, influenza, sleep disorders, and an area broadly classified as "respiratory health." In 2016, tuberculosis was added to the eligible diseases list. TB was eligible for funding support in FY 2012 but was removed in later years. When TB advocates discovered this opportunity, they urged Congress to return the airborne infectious disease, highly prevalent in some countries that U.S. forces operate in, such as Indonesia, to the list of eligible diseases.

The PRMRP and CDMRP's support medical research projects of scientific merit and direct relevance to the health care needs of military service members, veterans and/or beneficiaries. The program supports basic science and translational research; novel product development leading to improved therapeutic or diagnostic tools; synergistic, multidisciplinary research programs and clinical trials that address an immediate clinical need.

Congress also provided a 12 percent funding increase for the CDMRP's lung cancer program, putting funding at $12 million for DOD lung cancer research in 2016. There are two other areas within the CDMRP that have specific restricted allocations that provide obvious opportunities for pulmonary researchers including: Gulf War Illness (including respiratory illness) and Tuberous Sclerosis.

For more information about the PRMRP or other CDMRP-administered programs, visit the CDMRP website (http://cdmrp.army.mil/).Requests for email notification of the Program Announcements release may be sent to help@cdmrp.org. ■

CHILD HEALTH RESEARCH

ECHO Children's Environmental Health Opportunities Now Open

The NIH's new Environmental Influences on Child Health Outcomes ECHO initiative is now open and accepting letters of intent until March 15, 2016. ECHO is a seven-year-long trans-NIH program, involving the National Institute of Child Health and Development, the National Institute of Environmental Health Sciences, and the Office of the NIH Director, which was created following the ending of the National Children's Study.

The program will differ from the NCS in that it will use existing research cohorts to study short and long-term impacts of physical, chemical, biological, social, behavioral, natural and built environmental exposures on children's health and development, including early life exposures. ECHO will focus on four high-impact public health outcome areas including obesity, neurodevelopment, upper and lower respiratory disease, and birth outcomes, including prenatal, perinatal, and postnatal development.

The studies will share standardized core data elements managed by a central coordinating center and an associated data analysis center. The core elements to be included across all studies are:

- Demographics
- Typical early health and development
- Genetic influences on early childhood health and development
- Environmental factors
- Patient/Person (parent and child) Reported Outcomes (PROs)

View ECHO's seven funding opportunities here. Letters of Intent are due on March 15 with applications due on April 15. ■

PCORI NEWS

PCORI Board Approves Three New Lung Research Initiatives

At its Jan. 26 meeting, the Patient-Centered Outcomes Research Institute approved $70 million in nine new research projects, including three on lung disease and prevention. The awards are part of PCORI's initiative supporting "pragmatic clinical studies." These studies, conducted in routine clinical settings, aim to produce outcomes that are more relevant to a broad range of patients and care settings and easier to translate to clinical practice.

One of the newly funded studies is the Roflumilast or Azithromycin to Prevent COPD Exacerbations (RELIANCE) study at the University of Illinois at Chicago. The study will examine the effectiveness of roflumilast and azithromycin in the treatment of patients with COPD. No studies to date have directly compared long-term roflumilast to azithromycin in patients with COPD, so it is currently unclear how well they work when compared to each other.

Another study, the Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations (PESRAMHIP), conducted through Brigham and Women's Hospital, will study the effectiveness of the new Patient Activated Reliever-Triggered Inhaled CorticoSteroid (PARTICS) along with provider education, versus daily use of an inhaled corticosteroid in African American and Hispanic adults with asthma. In small studies in "controlled" situations, the PARTICS strategy has shown effectiveness at controlling asthma

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and preventing exacerbations. It remains unclear how well it works in real-world situations.

The third new lung-related study, through Massachusetts General Hospital, is prevention-based. It will look at the effectiveness of different approaches involving community health workers, targeted education, and other strategies to help adults with serious mental illness to stop smoking. Smoking rates among people with SMI are 53 percent. Although effective treatments have been identified in clinical trials, they are not routinely offered by to patients with SMI by primary care and psychiatric providers. The intervention to be studied aims to change this by providing targeted education to prescribers, as well as community health workers to strengthen tobacco cessation efforts. If successful, the intervention could be implemented for people with SMI through state Medicaid programs, mental health departments, and private health insurance. ■

RESEARCH FUNDING

President Obama Unveils Proposed 2017 Budget

On Feb. 9, 2016, the president released his proposed budget for Fiscal Year 2017. The president's budget is the first step in the 2017 spending process and serves as a guideline for the congressional appropriations committees, who will begin drafting FY 2017 spending bills within the next few months.

NIH

The president's 2017 budget proposes an $825 million funding increase over the FY 2016 level for the NIH, although these funds are targeted to the vice president's Cancer Moonshot initiative, the Precision Medicine initiative, and the BRAIN initiatives. With the exception of the NCI, all other NIH institutes are flat funded in the president's proposed budget.

While the flat funding for all but a few NIH areas is not welcome news, no one expects Congress to adopt the president's spending allocations for NIH (or other programs for that matter). The ATS Washington DC Office staff expects that Congress will provide more balanced increases for all NIH Institutes.

The health research initiatives featured in the president's FY 2017 budget are:

- Vice President's Cancer Moonshot Initiative. The budget proposes a multi-year initiative with $680 million proposed for the NIH in FY 2017 to expand clinical trials for health disparity populations, pursue new vaccine technology, and fund opportunities in cancer research.
- Precision Medicine Initiative. The budget proposes $300 million for NIH, an increase of $107 million above FY 2016, to support development of a research cohort of more than a million individuals to gather data on the interplay of environmental exposures, physical parameters, and genetic information.
- AHRQ Evidence-based Healthcare Practice. The president's budget proposes an increase of $24 million for health services research at the AHRQ to further develop the evidence base of effective practices. Additionally, $9 million is proposed for a new AHRQ project to better coordinate care for patients with multiple chronic conditions by developing and piloting tools based on integrated care plans.

CDC

Under the FY 2017 budget proposal, CDC's overall funding level is slated for a $194 million funding cut compared to FY 2016. The proposed budgets for the CDC programs that the ATS monitors are:

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Research Funding *(Continued from page 12)*

- Asthma—Flat funding at the FY 2016 level of $29 million
- National Institute of Occupational Safety & Health—a proposed $53.5 million funding cut over the FY 2016 level for proposed funding of $285 million
- Tobacco—Flat funding at the FY 2016 level of $210 million
- Domestic tuberculosis control—Flat funding with the FY 2016 level at $142.2 million.

Antibiotic Resistance

The budget proposes to further expand the administration's Antibiotic Resistance detection, treatment and prevention efforts through CDC, NIH, FDA, VA, and USDA. The FY 2017 budget proposes $877 million, an increase of $43 million over FY 2016, to continue expanding the nation's ability to fight antibiotic resistance, aligning with the Administration's National Action Plan for Combating Antibiotic-Resistant Bacteria. These investments will implement interventions to reduce the emergence and spread of antibiotic-resistant pathogens. In addition, the funding will support ongoing research aimed at developing new drugs and diagnostic products.

VA Research Program

The president's FY 2017 budget includes $663.4 million for VA Medical and Prosthetic Research, a $32.7 million (5.2 percent) increase over the FY 2016 enacted level.

USAID TB

The FY 2017 budget proposes a significant 19 percent funding cut to USAID's TB program, despite the release of the National Action Plan to Combat MDR-TB, a plan with ambitious targets over five years for treating 200,000 global MDR patients and reducing MDR-TB in the U.S. by 15 percent by 2020. This is the third year in a row that the administration has proposed this cut to the TB program.

EPA

The president's FY 2017 budget proposes $8.3 billion for the EPA, about $200 million over the FY 2016 funding level of $8.1 billion. ■