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Letter from the Editor

The June Research News Quarterly continues our interview series with National Institutes of Health and federal program heads, featuring a conversation with the chief of the Field Studies Branch in the Respiratory Health Division of the National Institute for Occupational Safety and Health at the Centers for Disease Control, Kristin J. Cummings, MD, MPH. In this interview, Dr. Cummings outlines the NIOSH's efforts to improve our understanding of occupational respiratory diseases and how to prevent them, which includes health workplace investigations and supporting investigator-initiated morbidity and mortality studies of respiratory and other conditions in worker populations.

Next, we have an update on the Research Advocacy Committee's recent Hill Day in Washington, D.C., followed by a report on the ATS's response to the National Heart, Lung, and Blood Institute's draft strategic research priorities and a feature by Veterans Affairs Subcommittee co-chair James Brown, MD, on the VA's Career Development Program.

Next, we move to other NIH institute news, beginning with the National Institute of General Medical Sciences (NIGMS) announcement of the new director of Pharm., Physiology & Biological Chemistry Division and then to the National Institute of Environmental Health Sciences (NIEHS) for a report on the availability of a new resource to assist researchers study child environmental exposures.

The June Research News Quarterly is concluded with reports from our Washington office on the progress of 2017 NIH and health agency funding and a recent successful effort in the U.S. Senate to protect the Department of Defense biomedical research programs.

Sincerely,

Linda Nici, MD Editor



INTERVIEW WITH KRISTIN J. CUMMINGS, MD, MPH

Chief, Field Studies Branch, Respiratory Health Division, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention

Q: What are the goals and focus of the Field Studies Branch of the Respiratory Health Division of NIOSH?

A: NIOSH's overall mission is to generate new knowledge in the field of occupational safety and health and to transfer that knowledge into practice for the betterment of workers. The Field Studies Branch (FSB) in the Respiratory Health Division (RHD) at NIOSH focuses on understanding and preventing occupational respiratory diseases, including novel diseases from exposures not previously recognized as hazardous. We conduct investigations of workplaces at the request of the public (health hazard evaluations) or other agencies (technical assistance). We also conduct investigator-initiated morbidity and mortality studies in selected worker populations and the general population to identify causal agents, quantify exposure-effect relationships, and evaluate frequency and severity of specific respiratory diseases. As part of this work, we develop and evaluate research tools, including pulmonary function tests, air sampling approaches and equipment, and biomarkers of exposure and health effects, and protective measures.

Q: How does the branch determine when a field study investigation is warranted?

A: Every year, NIOSH receives hundreds of requests for health hazard evaluations from workers, unions, or employers. Those that involve respiratory health may be assigned to FSB. Many requests address an exposure or respiratory health outcome that is well understood and for which preventive measures have been established. In those cases, we are able to provide guidance without making a site visit. In other cases, where the exposure or respiratory health outcome is novel or not well characterized, we cannot make a determination of whether a

Kristin J. Cummings Interview (Continued from page 2)

health hazard exists and provide recommendations for prevention without performing a field study.

Most recently, we have been evaluating coffee processing facilities, due to concerns about exposure to flavoring chemicals including diacetyl. Diacetyl is the butter-flavoring chemical that was found to have caused obliterative bronchiolitis in microwave popcorn workers about 15 years ago. In 2012, we evaluated a coffee processing facility where five workers developed obliterative bronchiolitis. They all had worked in the flavoring room, adding flavorings to roasted coffee. We found elevated levels of diacetyl and a related substitute chemical, 2,3-pentanedione, in the air in the flavoring room, but also outside of the flavoring room, where coffee beans were roasted, ground, and packaged. We learned that roasting and grinding coffee naturally generate these chemicals, which may pose a hazard to workers even in facilities producing only unflavored coffee.

Health hazard evaluations tend to be relatively shortterm and narrowly focused on the requestor's concerns. We also conduct longer-term field studies that allow us to address a broader set of research questions relevant to occupational respiratory disease. In some cases, these investigator-initiated studies are stimulated by the findings of a health hazard evaluation. For instance, we are studying the long-term health outcomes of workers at the sentinel microwave popcorn plant where the link between diacetyl and obliterative bronchiolitis was originally identified. Similarly, a health hazard evaluation at an indium-tin oxide (ITO) production facility where two workers were diagnosed with pulmonary alveolar proteinosis prompted a longer-term study to characterize early biomarkers of exposure and adverse respiratory health effects. In both of these field studies, we have partnered with local providers to offer study participants high-resolution computed tomography, in addition to pulmonary function tests and blood tests, that we can conduct in the field.

In other cases, a longer-term field study is designed to address an occupational respiratory health issue that has come to our attention through surveillance activities of RHD's Surveillance Branch and state partners, or because of the findings of other researchers. Work-related asthma is the most common occupational respiratory disease. In the past, we conducted a series of collaborative studies to identify the causes of work-exacerbated asthma. More recently, multiple information sources indicated an emerging cause of work-related asthma is cleaning and disinfecting activities in health care facilities. As a result, we are conducting a field study to characterize these complex exposures and their health effects. focusing in particular on real-time monitoring. Ultimately, our goal is to be able to provide health care facilities with evidence-based guidance on how to better protect the respiratory health of workers who clean and disinfect.

Q: How do you envision collaboration between the ATS and NIOSH Respiratory Health Division?

A: The ATS and the NIOSH RHD have a long history of collaboration. Members of the RHD (previously called the Division of Respiratory Disease Studies) have played leadership roles in the Environmental, Occupational, and Population Health Assembly and have led or participated in key workshops and task forces, including those that led to ATS documents on the Occupational Contribution to the Burden of Airway Disease, Work-Exacerbated Asthma, Spirometry in the Occupational Setting, and Diagnosis and Management of Beryllium Sensitivity and Chronic Beryllium Disease. In addition, the division plays an important role in disseminating ATS criteria for standardization and interpretation of spirometry, as it is tasked with approving courses for spirometry technicians under several Occupational Safety and Health Administration standards and approving spirometry providers under the new Respirable Coal Mine Dust Rule. Furthermore,

Kristin J. Cummings Interview (Continued from page 3)

the division's role in overseeing pulmonary function tests such as spirometry and exhaled nitric oxide in the National Health and Nutrition Examination Survey (NHANES) has provided ATS members with population-based clinical reference values and research opportunities. Most recently, the ATS convened a panel of experts to develop a knowledge base to support the development of a clinical decision support tool to improve the recognition of work-related asthma in the primary care setting.

Moving forward, RHD will be focusing on strategic development for the third decade of the National Occupational Research Agenda (NORA). We will be asking our stakeholders, including the ATS and its members, to help us address the following questions: What issues in work-related respiratory disease will cause the greatest burden of morbidity, mortality, and cost over the next decade? What emerging issues have the potential to add to that burden? What should be done to address those issues and reduce their burden during the third decade of NORA? The answers to these questions will help to guide priorities for both intramural and extramural NIOSH funding. We expect that the ATS and its members will make critical contributions to this process.

Q: Is the Field Studies Branch under the purview of both the NIOSH and CDC—when and how is your branch involved with the CDC epidemic intelligence service?

A: NIOSH is part of the CDC. RHD is part of NIOSH and an active participant in the Epidemic Intelligence Service (EIS) training program (http://www.cdc.gov/eis/) as well as other CDC training programs and fellowships. RHD trains EIS officers from a range of backgrounds, including medicine, nursing, epidemiology, and industrial hygiene. EIS officers who come to FSB learn how to conduct epidemiologic investigations focused on the respiratory health of workers. They work as part of a multidisciplinary team to characterize workplace exposures and respiratory health, and understand the relationship between work and disease. The EIS program is a unique learning experience, and many graduates decide to stay on with CDC afterwards. I myself got started in this field as an EIS officer in FSB back in 2005. I thought I would stay just for the twoyear training program, but found that I loved the work and didn't want to leave when it was over.

Q: How is the branch usually notified of a potential occupational health-related issue?

A: We are notified of potential occupational respiratory health issues in a variety of ways. Our authority to evaluate individual workplaces is based on formal requests for health hazard evaluations from current workers, unions, and employers and requests for technical assistance from other federal, state, and local agencies. But other sources of information are also critical to identifying occupational respiratory health issues. For example, we also hear from former workers: people who became ill while working and left employment, or who developed disease after leaving a workplace, and wonder if an exposure at work was responsible. Surveillance by RHD's Surveillance Branch and state partners identifies sentinel events, such as a cluster of work-related asthma in a syntactic foam manufacturing facility or a case of silicosis related to guartz countertop fabrication. One of our most critical sources of information is physicians: astute clinicians who delve into a patient's occupational history and recognize a possible connection, or who see several patients from the same workplace with the same problem. Physicians who want to report a potential issue can contact FSB at 304-285-5751 or 800-232-2114.

RESEARCH ADVOCACY NHLBI UPDATE **ATS Committee Advocates for** Research Funding on Capitol Hill Strategic Vision

In late April, members of the ATS Research Advocacy Committee, chaired by Linda Nici, MD, and the Public Advisory Roundtable (PAR) came to Washington, D.C. to advocate for increased health research funding with their members of Congress. Committee members traveled from Alabama, Arizona, California, Illinois, Indiana, Maryland, Michigan, Pennsylvania, Rhode Island, and Tennessee to meet with more than 28 Senate and House offices including personal meetings with Sen. Jack Reed (D-RI) and Representative David Cicilline (D-RI).

The committee came to Washington, D.C. to call for increased funding for the NIH, CDC, including the asthma, tuberculosis and National Institute of Occupational Safety and Health programs, and the VA Research program. Additionally, ATS members called for passage of legislation to help veterans exposed to burn pits and support young researchers.



Veena Antony, MD, Representative David Cicilline (D-RI) and Linda Nici, MD

The ATS Comments on NHLBI

The NHLBI's process to develop a new strategic vision plan to guide the institute's research priorities is moving towards the final stage, with a final strategic plan to be released this summer. In February 2016, the institute released its draft research priorities, organized broadly through four overall strategic goals and eight corresponding objectives, for public comment. The most extensive part of the document is the draft list of compelling questions and critical challenges, organized in alignment with the goals and objectives. The NHLBI's draft strategic goals are:

- 1) Understanding human biology;
- 2) Reduce human disease;
- 3) Advance translational science; and
- Develop workforce and resources

The ATS Research Advocacy Committee reviewed the NHLBI strategic research priorities and in consultation with the ATS Executive Committee, developed recommendations on behalf of the society. The committee found that the priority draft provided a good framework to guide the institute's science over the next decade, but recommended increased emphasis on respiratory disease, critical illness and sleep disorders in proportion to their growing public health burden in the U.S. and globally, beginning with the origins of lung disease from prenatal development through childhood. The ATS identified the development of non-invasive biomarkers to assess disease activity and therapy response and greater understanding of the genetic, epigenetic and environmental influences as key critical challenges in this area. The ATS also urged additional prioritization for rare diseases among the NHLBI's

NHLBI Update (Continued from page 6)

priorities, specifically recommending examination of the pathobiologic pathways to overlap syndromes, such as asthma-COPD syndrome and combined pulmonary fibrosis with emphysema.

In keeping with the ATS's strong focus on strengthening the scientific workforce, the Society urged the NHLBI to provide a strong and clear emphasis in its strategic priorities on the critical challenges of maintaining financial support and career stability to young investigators. The ATS wrote, "In order to truly sustain the heart, lung and blood workforce, we need a stronger and more unified effort to identify new funding streams, better collaborative funding opportunities between government and the public/private sector, and consideration for additional debt forgiveness such that newly graduated physicians can financially afford to continue their scientific investigation and contribute to the advancement of medicine."

View the NHLBI strategic research priorities draft here. The ATS will inform members when the institute's final strategic vision is released.

RESEARCH OPPORTUNITIES

VA Career Development Award-2 (CDA-2)

James K. Brown, MD, co-chair, ATS VA Subcommittee & member, Research Advocacy Committee

For young pulmonary investigators late in their fellowship training, the VA Career Development Award (CDA-2) provides salary and/or project funds to support a three to five year mentored program of research and training. Applicants are usually at the Assistant Professor level. The goal of the program is to attract, develop, and retain talented clinicians and non-clinicians to conduct mentored research in areas of particular importance to the VA and Veterans health care. Awardees gain mentored research time intended to advance awardees to independence as VA scientists. For clinicians, it is expected that the awardee will spend approximately seventy- five percent of their time in research and twenty-five percent of their time in patient care and clinical education. The VA Office of Research & Development makes these awards available in all four Services, which are Biomedical Laboratory (BLR&D), Clinical Sciences (CSR&D), Health Services (HSR&D), and Rehabilitation R&D Service (RR&D). The application process begins with the submission of a Letter of Intent (LOI). LOI deadlines are May 1 and November 1 for BLR&D, CSR&D and RR&D and April 15 and October 15 for HSR&D. Eligibility requirements include the following:

- · United States citizenship is required
- Applicants need not be VA employees at the time of application but they must be nominated by a VA and they must have a VA appointment in place at the start of funding.
- Clinicians must be no more than 5 years past their last clinical training and no more than 10 years past receipt of their MD.
- Non-clinicians must be no more than 5 years beyond receipt of their terminal degree (e.g. Ph.D).
- Applicants must have at least one or more authored peer-reviewed publication pertinent to the proposed area of study.
- Applicants should carefully identify mentors, of which at least one must be a local VA-funded investigator and have a well-defined role in both the research and training proposed. At least some of the proposed research must be carried out in the VA-based mentor's laboratory.

Further information can be found at: http://www.research.va.gov/services/shared_docs/ career_dev.cfm

NIGMS UPDATE NIGMS Names New Director of Pharmacology, Physiology & Biological Chemistry Division

In June, the National Institute of General Medical Sciences (NIGMS) announced the appointment of Rochelle Long, PhD. as the new director of the Division on Pharmacology, Physiology and Biological Chemistry (PPBC). This NIGMS division funds a broad array of research from basic science in synthetic chemistry and chemical biology to sepsis and traumatic injury.

Dr. Long is well known for her emphasis on promoting multi-disciplinary scientific collaborations. She is the recipient of an NIH Director's Award for her leadership in establishing the trans-NIH Pharmacogenomics Research Network, a team of scientists around the U.S. working on understanding genetic contributions to drug response. Dr. Long began her career with the NIGMS in 1990 as a program director in the PPBC, becoming chief of the Pharmacological Sciences Branch in 1998. She earned her PhD in pharmacology from the Uniformed Services University of the Health Sciences.

CHILD HEALTH

NIEHS Launches New Resource for Children's Environmental Health Research

In June, the National Institute for Environmental Health Sciences (NIEHS) announced the launch of a new tool for research on child environmental health called the Children's Health Exposure Analysis Resource (CHEAR). The resource was developed to help child health investigators expand their studies to consider environmental impacts through laboratory and data analysis. CHEAR will analyze biological samples for chemicals and biomarkers of exposures at no cost to NIH-funded researchers.

CHEAR is composed of the following three specific elements:

- The National Exposure Assessment Laboratory Network, which will conduct laboratory analyses for specific environmental exposures, such as pesticides or metals. The labs can measure biological markers of impacts from environmental conditions which children or their parents are exposed to, such as markers of inflammation. The Lab Network is centered at six institutions throughout the U.S., including Emory University, the Icahn School of Medicine at Mount Sinai, Research Triangle Institute in North Carolina, the University of Michigan, the University of Minnesota, and Wadsworth Center in New York.
- The Data Repository, Analysis and Science Center, at the Icahan School of Medicine, which will manage the storage of CHEAR data, provide consultation on statistical analyses and facilitate the development of new statistical methods and informatics tools.
- Finally, CHEAR will have a Coordinating Center at Westat, Inc. in Maryland, to direct the application process and provide technical assistance to researchers using CHEAR.

Researchers can apply to use the CHEAR system continuously throughout the year and applications will be reviewed several times annually. Proposals should include a summary of the original study that collected samples and the proposed CHEAR analyses, including main research questions and their connection to child health. Visit the CHEAR website for application submission and more information at:

https://chearprogram.org/access/application-andreview-process

RESEARCH Senate Panel Approves NIH Funding Increase

In June, the Senate Appropriations Committee passed the fiscal year 2017 health research spending bill, known as the Labor-HHS bill, following subcommittee passage earlier that week. The bill includes an overall \$2 billion funding increase for the NIH over the FY2016 level of \$32.084 billion, for a total proposed FY2017 level of \$34.084 billion. Of this funding increase, about \$1.4 billion is proposed to be allocated for the Precision Medicine Initiative, Alzheimer's research, the BRAIN Initiative and the Institutional Development Award (IdEA). The remaining \$546 million would be distributed across individual NIH institutes.

The Senate's proposed spending bill is a significant improvement over the President's FY2017 budget, which proposed a \$1 billion increase for NIH, but all of this additional funding was allocated to the PMI, BRAIN, Alzheimer's and IdEA initiatives. The following are funding levels for the NIH institutes that the ATS monitors:

- A \$245.6 million funding increase for the National Institute of Allergy and Infectious Diseases, for a proposed FY2017 funding level of \$4.961 billion
- A \$129 million funding increase for the NHLBI, for a proposed funding FY2017 level of \$3.242 billion
- A \$44 million funding increase for the NIGMS, for a proposed F2017 funding level of \$1.776 billion
- A \$57.4 million funding increase for the National Institute of Child Health and Development (NICHD), for a proposed FY2017 funding level of \$1.395 billion
- A \$28.7 million funding increase for the National Institute of Environmental Health Sciences (NIEHS), for a proposed FY2017 funding level of \$722 million

• A \$6 million funding increase for the National Institute of Nursing Research (NINR), for a proposed funding level of \$151.9 billion.

The CDC does not fare as well in the Senate bill, however, and is slated for a \$118 million funding cut overall, reducing funding from the FY2016 level of \$7.233 billion to \$7.115 billion. CDC programs that the ATS monitors are also slated for cuts. The following are proposed funding levels for CDC programs that the ATS monitors:

- Flat funding for the asthma program at the FY2016 level of \$29 million
- A \$5 million proposed cut for the tuberculosis program, reducing funding from \$142.2 million in FY2016 to \$137.2 million
- A \$5 million proposed cut for the NIOSH over the FY2016 level, but an improvement over the President's FY2017 proposal to cut \$126 million from the program.
- Flat funding for the tobacco program at the FY2016 level of \$210 million.

The Labor-HHS bill passed both the subcommittee and full appropriations panels on bipartisan votes for the first time in seven years. This is because the bill is free of partisan policy riders such as measures defunding the Affordable Care Act which precluded bipartisan support. But it is important to note that Senate committee actions are the first congressional procedural steps for the 2017 health spending bill. From this point onwards the bill's progress is unclear. The House Labor-HHS subcommittee, chaired by Rep. Cole (R-OK), has announced that the subcommittee's vote will be the week of June 20. Following House committee action, Congress will have to work out all of the spending bills in an election year, which is a difficult task. So, while we cannot say at this point what level of a funding increase the NIH will receive for 2017, there is now good bipartisan agreement that there will be a funding increase across all NIH institutes.

DOD RESEARCH Senate Votes to Maintain

Defense Department Biomedical Research Program

In June, the Senate voted down an attempt to significantly narrow the Department of Defense's Congressional Directed Medical Research Program (CDMRP). Since its creation in 1992, the CDMRP has supported medical research to benefit military service members, their families and veterans. The CDMRP's groundbreaking research has led to advances in our understanding and detection of traumatic brain injury and new therapies for breast cancer and prostate cancer. The program currently supports research in pulmonary fibrosis, lung cancer, constrictive bronchiolitis, influenza, acute lung injury, sleep disorders, respiratory health, and tuberculosis. The National Defense Authorization Act, S. 2943, a Senate bill that reauthorizes most Department of Defense programs, included language inserted by Sen. McCain (R-AZ), chair of the Armed Services Committee, that would have eliminated much of the CDMRP's research. The measure would have significantly limited the range of diseases and conditions that could be studied and additionally, require research grants to comply with complex acquisition compliance and auditing procedures currently reserved for large defense contracting companies. Sens. Durbin (D-IL), Cochran (R-MS) and a bipartisan group of fifteen senators sponsored a Senate floor amendment to eliminate the restrictions on the CDMPR from the Defense bill. The Senate passed the Durbin-Cochran amendment by a vote of 66 to 32. The House version of the Defense bill does not include the restrictive CDMRP language. The ATS worked with a coalition of research groups to oppose Sen. McCain's measure and sent a letter to all senators urging them to support the Durbin-Cochran amendment.