

Research News Quarterly

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Letter from the Editor

The June ATS Research News Quarterly features an interview with the Director of the National Institute of Environmental Health Sciences (NIEHS), Linda Birnbaum, PhD. Dr. Birnbaum shares her vision for the institute over the next five years, how sequestration funding cuts are affecting the institute and some of the NIEHS's focus areas in lung disease.

This month's Quarterly also features a report on a discussion that the ATS Research Advocacy Committee were fortunate to have with NHLBI Director Gary Gibbons, MD, at the 2013 ATS Conference in Philadelphia, followed by the outlook for health research and services funding for FY2014 and the release of a new NIH factsheet on the impact of sequestration on the agency's research.

Next, the VA Subcommittee of the Research Advocacy Committee reports on how ATS members can use the VA laboratory infrastructure report released in August 2012 to advocate for funding for VA laboratory infrastructure in your state and throughout the VA system. Finally, we report on new research grants awarded by the Patient Centered Outcomes Research Institute (PCORI) in lung disease including end-of-life care and pulmonary fibrosis.

Sincerely,

Linda Nici, MD
Editor



AGENCY SPOTLIGHT – NIEHS

Interview with Linda Birnbaum, Ph.D., D.A.B.T, A.T.S., Director, National Institute of Environmental Health Sciences

Q. What is your vision for the institute over the next five years?

A. Beginning in 2011, the NIEHS began the process of developing a 5 year strategic plan. We brought a broad group of NIEHS stakeholders - including grantees, advocacy groups and communications people in to help develop the plan in a meeting close to our Raleigh-Durham campus. We also solicited visionary ideas via the website. We received over 10,000 web hits with visionary ideas. This feedback and the Stakeholder meeting helped us pull the plan together. On August 1, 2012, the new strategic plan was released. It provides themes and goals that NIEHS will be focusing on over the next 5 years. The new plan built upon the past strategic plan but included a much stronger focus on public health and prevention. Other strong focal points are on the environmental influences on diseases and the opportunities to prevent diseases from happening which can allow us to develop interventions to prevent diseases from further progression, and sometimes we can actually prevent diseases with this knowledge. The NIEHS's global leadership is also emphasized in this plan in the way that we encourage other institutes, other federal agencies and our counterparts around the world to join us in the NIEHS quest to understand and provide better human health. Finally, the NIEHS is very interested in population studies, the translation of our science into the public health and public policy arena. Throughout our efforts, we also strive to involve the general public in our work to improve public health.

Q. What impact are the sequestration funding cuts having on the NIEHS in FY2013?

A. Sequestration is having a terrible impact on our science. With our operating budget at 5.7% less than last year, we have had to do a lot of work to revise our budgets downward. Both intramural and extramural research programs are being cut. We have had a soft hiring freeze in effect for the past 2 years, filling only the highest priority positions. Some contract staff are being laid off and other contracts are being ended prematurely. NIEHS will fund about 30

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Agency Spotlight *(Continued from page 2)*

fewer new grants this year than originally planned. Non competing grants will be cut by an additional two percentage points. Jobs will be lost and we are not sure that these people will fully understand why. I'm very concerned that scientific research is becoming less attractive to younger scientists. We recently reduced our research project grant payline from 15% to 13%, which means we are funding only those investigators who score extremely well. I am trying not to cut the training grants because this is our pipeline for the future of biomedical research. I am also concerned that this year's level may become the new baseline for determining future budgets.

Q. Lung diseases are now the third leading cause of death in the U.S. What are the NIEHS's key focus areas in lung disease?

A. The NIEHS has strong focuses in asthma, COPD and lung cancer. We have an ongoing concern about air pollution. Although pollution levels have come down there are still pockets where it's very high. Indoor air pollution is another issue. The institute is a partner in the interagency Cook Stoves initiative. Overall, we are very interested in windows of susceptibility and the long-term effects of early life exposures – air pollutants and other chemicals are the triggers that impact the lung in utero or as an infant or child and these exposures will have long-lasting consequences.

I am tired of people making the point of asking whether it is genes or is it the environment? Because the answer is – it's always both. In some cases, the genetic contribution may drive the response and in others it may be the environmental contribution. We are beginning to understand that people with certain genetic polymorphisms are more at risk and susceptible from air pollution. Other people are more susceptible either because of genetics and or past history. At the NIEHS, we are passionate about understanding environmental impacts on disease

and disability so we can help guide better policy decisions.

Q. How do you envision NIEHS partnering with other institutions such as NHLBI to better address the impact of lung diseases?

A. We already partner with NHLBI and NIAID on the Inner-city air pollution/asthma studies. Jim Kiley, Director of the Lung Division at NHLBI, was involved in the development of our strategic plan. We do lots of work on asthma. We also partner in certain areas with NCI, FIC and NICHD at multiple levels through extramural and intramural programs. We partner extensively with EPA and are also partnering with FDA on tobacco issues.

Q. How does the NIEHS intramural program complement the extramural program?

A. We have a vision of "One NIEHS." All the various parts of the NIEHS are aware of each other and involve each other as we move forward. Some of the intramural program focuses are on asthma and ozone. The intramural program does not do so much on particulate matter (PM) but the extramural program does a lot of work on PM, including a partnership with the National Institute on Occupational Safety and Health (NIOSH) on inhaled chemicals. A key initiative of the National Toxicology Program (NTP) is on testing of compounds. A particularly important part of this effort is on nano-safety. Historically, we have not paid much attention to whether nano-materials are safe or not. For instance, these long, skinny fibers may do the same thing as asbestos. I expanded this initiative in 2010 to include both our intramural and extramural programs as well. There are also non-occupational fibers that we have concerns about and this is a coordinated effort across all parts of NIEHS. The Consortium looking at these issues meets once or twice a year and it involves the NTP and the intramural program. The NTP is already partnering and conducting studies with the FDA to look at some nano

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Agency Spotlight *(Continued from page 3)*

materials and dermal issues, and to provide materials to our extramural partners. In the intramural program, our Acting clinical director is Stavros Garantziotis, MD. Some of his work is looking at human pulmonary macrophages and their response to cerium oxide. A long range plan is to expose mild asthmatics to such nanoparticles.

Q. In the era of genomics and other “omics”, will NIEHS attempt to balance the needs for “environment” for gene/environment interactions?

A. We are doing a lot in the areas of genomics and epigenomics. We are beginning to move into the exposome, which is the totality of human exposure, is more complicated than genome. One of our intramural investigators, Stephanie London, is looking at enhanced susceptibility in asthma and ozone toxicity, especially in children. So, the intramural program has a strong focus on genomics and the extramural program is looking at how the environment and genome are working for or against each other. I am excited about the opportunities in epi-genomics as this is where the environment plays its biggest role.

Q. What are your plans to ensure the training of future researchers and leaders in areas relevant to the NIEHS mission?

A. We have increased the stipend for trainees and are trying not to cut training at all. We have got to keep the pipeline moving. We are also working to increase diversity. We have a small on-site program to bring in underrepresented minorities called the NIEHS Scholars Connect Program. The NIEHS does a lot of outreach to extramural grantees and the advocacy community to help get the mission out there. The NIEHS is a small institute and cannot solve every problem but we want to focus on the greater risk of diseases due to environmental interactions and stressors. ■

NEWS FROM NHLBI

NHLBI Director Meets with ATS Research Advocacy Committee

National Heart, Lung, and Blood Institute Director Gary Gibbons, MD, kept a very busy schedule at the ATS 2013 International Conference in Philadelphia. In addition to his talks at the President’s Symposium, Diversity Forum, and the ATS Science and Innovation Center, Dr. Gibbons met with the ATS Research Advocacy Committee, now chaired by Linda Nici, MD.

Dr. Gibbons and the committee discussed a number of issues, including the outlook for biomedical research in light of declining federal funding, the specific effects of budget sequestration funding cuts, health disparities, and Dr. Gibbons vision for addressing health disparities.

Concerning research sustainability, Dr. Gibbons responded that the NHLBI’s priority is on maintaining support for investigator-initiated fundamental science. He explained, however, that the institute must be “good stewards” of the scientific enterprise through competition.

Committee member James Klinger, MD, briefed Dr. Gibbons on the ATS’s advocacy to support NIH funding, including the committee’s Hill Day on April 24, 2013, and the ATS Hill Day on March 19, 2013. Between both of these events, ATS members from around the country met with more than 110 House and Senate offices urging support for the NIH budget. Dr. Gibbons thanked the committee for its advocacy and urged members to continue educating Congress that the current funding model will not sustain biomedical research and advancements for patients. Concerning sequestration, Dr. Gibbons responded that sequestration cut \$175 million from NHLBI’s budget. Despite this cut, the institute

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New from NHLBI *(Continued from page 4)*

recently increased the payline to 11 percent, up from 6 percent, and has increased the number of R01 grants.

Committee member Roberto Machado, MD, engaged Dr. Gibbons on health disparities, pointing out some of the disparities that exist in lung disease, such as high asthma rates among minorities. Dr. Gibbons responded that he is most concerned about the most vulnerable in our society, including children. “We need to address the compelling public health needs that are in all communities and populations—this is a major part of our strategic priority setting,” he said. Dr. Gibbons extended an invitation to the committee and to ATS to partner with the NHLBI on eliminating health disparities.

Dr. Nici asked Dr. Gibbons about the NHLBI’s direction on training, including the balance between supporting young investigators and mid-career level researchers. He stated that supporting training is a strategic priority for NHLBI and that he has tried to minimize the impact of federal funding cuts on training as much as possible. “It is critically important that we protect the research workforce pipeline—young investigators.” ■

ADVOCACY

ATS RAC Visits Capitol Hill to Advocate for Health Research Funding

In April, members of the ATS Research Advocacy Committee, chaired by Augustine Choi, MD, brought their message of the critical need to sustain NIH funding to Capitol Hill. Committee members traveled from Massachusetts, Mississippi, Illinois, California, Texas, and Rhode Island to Capitol Hill to meet with more than 25 Senate and House members and advocate for increased health research and services funding for the National Institutes of Health, Centers for Disease Control and Prevention, and the Veterans Administration Research Program, and stressed the need to improve the VA’s aging laboratory infrastructure.



From left: Katharine Kroner, Pulmonary Hypertension Association; Roberto Machado, MD; Robert Primus, chief of staff, Representative Michael Capuano; Augustine Choi, MD; Nuala Moore, ATS Washington staff.

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RAC members participating in Hill Day included Drs. Augustine Choi, Rajesh Baghat, David Corry, James Brown, James Klinger, Linda Nici, Roberto Machado, and Ms. Katharine Kroner, who represented the ATS Public Advisory Roundtable member the Pulmonary Hypertension Association. ■

RESEARCH FUNDING

FY2014 Spending Process Off to a Rocky Start

During June and July, the House and Senate appropriations subcommittees usually begin consideration of spending bills to allocate funding for federal programs in their jurisdiction for the next fiscal year. Some subcommittees, such as the House Military Construction/Veterans Affairs and Agriculture subcommittees, are already moving in this direction and have passed FY2014 spending bills.

However, there is currently a large obstacle to further progress on all FY2014 spending bills in the form of an overall funding gap between both chambers. The House and Senate passed very different budget outline bills in March, creating a \$91 billion difference in FY2014 spending. The chief reason the budget bills differ so much is that the House budget continues to implement sequestration funding cuts called for by the Deficit Control Act passed in 2011, while the Senate bill does not.

The spending allocation differences between the two chambers are no less significant at the subcommittee level, including for the Labor-Health and Human Services subcommittees, which draft the spending bill to fund health research and services programs, including the NIH and CDC, known as the Labor-Health and Human Services (LHHS) bill. In the House budget, the overall allocation for LHHS programs represents

an 18 percent cut from the FY2013 funding levels, and this is following sequestration funding cuts. The Senate has not released allocations for its individual subcommittees yet.

In April, President Obama released his proposed budget for FY2014. The president's budget, which is intended to serve as a guideline to the congressional appropriations committees, also does not implement spending cuts called for under the Deficit Control Act, so the Administration's budget also differs significantly from the House budget. The executive budget proposes the following funding levels for key agencies that the ATS monitors:

- An increase of \$471 million or 1.5 percent over the FY2012 funding level for the NIH in FY2014, for a total proposed funding of \$30.7 billion (sequestration cuts \$1.5 billion from NIH in FY2013).
- A reduction of \$432 million or 8.1 percent from the FY2012 funding level for the CDC in FY2014, for a total proposed funding level of \$5.293 billion.
- A decrease of \$296 million over the FY2012 funding level for the EPA in FY2014, for a total of \$8.153 billion. Clean air standard setting and enforcement programs see small increases and climate change, radon, and diesel retro fit programs are cut.
- A proposed \$3.5 million increase for the VA Research Program for a total proposed funding level of \$586 million in FY2014. The House Military Construction/Veterans Affairs subcommittee approved this funding level in its bill, which is now moving to a House floor vote.
- A reduction of \$45 million or 19 percent over the FY2012 funding level for United States Agency for International Development's tuberculosis program for a total of \$191 million.

In light of the \$91 billion gap in overall budgetary outlines, it remains to be seen whether both chamber subcommittees or only one will produce a FY2014 LHHS spending bill before Congress adjourns in

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Research Funding *(Continued from page 6)*

August. Although the House LHHS subcommittee, chaired by Rep. Jack Kingston (R-GA) has its overall budget, the subcommittee has not announced a date for consideration of a bill. The Senate appropriations subcommittees are known to be working on drafting FY2014 spending bills but have not announced committee vote dates either as the full chamber is working on immigration reform. The looming prospect of another showdown between Congress and the President over the debt ceiling in the fall will also affect the progress of FY2014 appropriations work.

The ATS Washington Office will keep members informed of the FY2014 spending process, including when ATS member action is needed to support health research and services funding. ■

NIH NEWS

NIH Releases Fact Sheet on Impact of Sequestration

The NIH has released a new fact sheet detailing the impact of sequestration on the agency. The factsheet points out the following:

- Sequestration cuts 5 percent or \$1.55 billion from the NIH budget in FY2013
- The impact on NIH's intramural research is substantial because the funding cuts are applied retroactively to spending since Oct. 1, 2012, so the effect can be up to 10 percent since the funding has to be absorbed in less than half a year.
- 700 fewer competitive research grants are being funded by NIH in 2013
- About 750 fewer new patients would be admitted to the NIH Clinical Center
- The NIH-wide average cut to research project grants is 4.7 percent. ■

VA RESEARCH PROGRAM

Update on the VA Research Infrastructure Report

As reported previously, in August 2012, the VA released its long-awaited "Final Report of the VA Research Infrastructure Program." The Congressionally mandated report provides a detailed survey of research laboratories in 74 VA medical centers. It describes an estimated \$774 million in critical laboratory renovations that are needed. About 44 percent of the estimated costs of these renovations constitute "Priority 1" deficiencies—those with an immediate need for correction to return components to normal service or operation, stop accelerated deterioration, replace items that are at or beyond their useful life, and correct conditions hazardous to investigators.

The ATS Government Relations Office is working to help secure funding to correct these deficiencies. Recently, members of the ATS's Research Advocacy Committee visited more than 20 Congressional offices in Washington, D.C., to urge Congress to provide funds to address VA laboratory infrastructure. ATS members sought \$50 million for major and \$175 for minor construction projects to begin to address the infrastructure deficiencies outlined in the report. The Association of Medical Colleges has posted the full VA laboratory infrastructure report.

ATS members who work at VA facilities are encouraged to do the following:

- 1) Review the infrastructure recommendations for your facility.

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VA Research Program *(Continued from page 7)*

- 2) If the report notes priority 1 or priority 2 deficiencies, share a copy of the report with your program director.
- 3) Contact your Congressional delegation to make them aware of the report and the recommendations it makes for your facility.

If you are a VA employee, your interactions with members of Congress and their staff must be done as a private citizen and must be done on non-VA time. ■

PCORI to Fund Over 50 New Patient-Centered Studies

The Patient-Centered Outcomes Research Institute has announced funding approvals of 51 new patient-centered research projects. The new approvals along with projects approved by the PCORI Board in 2012 amount to \$129.3 million in patient-centered outcomes

research projects being funded by the institute. The new awards include a number of research projects on asthma, lung cancer, end-of-life care, and pulmonary fibrosis, including the following:

- Health System Intervention to Improve Communication About End-of-Life Care for Vulnerable Patients; lead investigator, J. Randall Curtis, MD, University of Washington; and
- Patient Participation Program for Pulmonary Fibrosis: Assessing the Effects of Supplemental Oxygen; lead investigator Jeffrey Swigris, DO, MS, at National Jewish Medical Center in Colorado.

PCORI's released another funding announcement on May 15. In this cycle, one grant will be awarded in each of the PCORI 5 national priority areas and awards will be announced in August. More information about the new award approvals and the August funding cycle can be found at the PCORI website. ■