

On April 11<sup>th</sup>, the House Subcommittee on Labor, HHS, and Education held a hearing examining the FY19 budget request for the National Institutes of Health. Although the only official witness on the agenda was NIH Director Dr. Francis Collins, he was accompanied by several institute directors:

- Dr. Francis Collins: Director of National Institutes of Health
- Dr. Norman Sharpless: Director of National Cancer Institute
- Dr. Anthony Fauci: Director of National Institute of Allergy and Infectious Diseases
- Dr. Diana Bianchi: Director of National Institute of Child Health and Development
- Dr. Nora Volkow: Director of National Institute of Drug Abuse

A webcast of the hearing can be found [here](#) and Dr. Collins' opening statement is attached. Below is a summary of the major areas of discussion at the hearing.

#### **OPENING STATEMENTS:**

Chairman Tom Cole (R-OK):

- Though NIH funding increased by \$3 billion in FY18 to increase discoveries, don't expect that again in FY19.
- I am concerned requested levels in FY19 would hinder the medical research community from making key discoveries.
- The Committee's goal is to continue to position US as the world's leader in biomedical research.

Ranking Member Rosa DeLauro (D-CT):

- NIH work is absolutely lifesaving. One breakthrough can save millions of lives over generations.
- Congress must restore NIH's budget. But I am concerned the FY19 budget would reduce that figure drastically. It would turn back the clock.
- I am pleased the NIH is striving to end addiction and invest in non-opioid pain management.

Full Committee Chairman Rodney Frelinghuysen (R-NJ)

- Congress has provided NIH with a great deal of funding.
- "The NIH purse is full," and Congress wants it to be spent well with the maximum benefit to the American people.

Director Francis Collins:

- We must foster the next generation of scientific discovery and remain world leader in biomedical innovation.
- It all lies in five areas.
  - Stable support after decade long freeze in funding.
  - Vibrant workforce behind new grants.
  - Computational power (including individualized medicine like microbiome)
  - New technology like gene therapy, immunotherapy require new facilities.
  - Scientific inspiration

#### **QUESTION AND ANSWER:**

Chairman Cole:

- Will NIH continue ongoing Down Syndrome research?
  - Bianchi: We have developed a proposal on how we plan to spend that new funding. We are working with NCATS to ensure the basic research is translational for clinical care.
- Congress provided a lot of money for the Cancer Moonshot. What your plans this year?

- Sharpless: We have 10 areas of focus with rapid translation to clinical care. This includes immunotherapy, checkpoint inhibitors, and early detection.
- What is NIH doing on addiction mitigation?
  - Volkow: We are funding pain management and working on an addiction vaccine. We are putting resources into the most meritorious projects. We cannot afford to wait.

Ranking Member DeLauro:

- This year was the worst flu season in more than a decade. Congress provided \$100 million to develop a universal flu vaccine. What are the “knowledge gaps” we are facing?
  - Fauchi: We are trying to harvest the DNA sequence of the flu which does not change from season to season. It will require several years more of work and more funding, but we are moving to fill those knowledge gaps.
- Maternal mortality statistics are horrible, especially among African American women. What is happening?
  - Bianchi: We are very concerned. We are researching how to stop it. Much of it is cardiovascular, diabetes, depression, and other preexisting conditions. We are working with FDA to test drugs during pregnancy.

Rep. Chuck Fleischmann (R-TN)

- The FY19 budget proposal plans to transfer Energy Employee Occupational Illness Compensation Program activities from the Department of Labor to NIH. There is little justification for this move. Why did the Department do this?
  - Collins: We are not particularly familiar with EEOICP. We need to examine this proposal more, though it seems to be working fine current.
- Most members of Congress support research of synthetic opioids. Are you concerned restrictions on Class I banned substances will hurt compound research activities?
  - Collins: Yes, we are.
  - Volkow: Yes, we need to research the drugs, and that is a lengthy process. We are working with the DEA on this. We need countermeasures to synthetic opioids quickly and cannot afford delays.

Rep. Lucille Roybal Allard (D-CA)

- I am concerned about recent NIH decision to stop research into the effect of alcohol advertising on human health among children. This reportedly involves a private solicitation from the alcohol industry. Who is responsible? And why did NIAAA make this decision?
  - Collins: We are concerned about this report. We have some facts, but are digging deeper. It has our greatest attention and may go to the Inspector General. NIH must not be influenced. We also must ask scientific question about the effect of alcohol consumption on human health.

Rep. Andy Harris (R-MD)

- Following on Rep. Roybal Allard, I believe public private partnerships leverage federal funding to fund additional research. People think marijuana is a “cure-all” but there is not medical evidence. Is there any evidence medical marijuana is effective at treating opioid addiction?
  - Volkow: No study has shown that.
- I am concerned about the aging workforce at NIH. The average RO1 investigator is 45. Most medical breakthroughs come from research done in younger years.

- Collins: I agree. We must work with universities on new programs for new innovators.
- NIH must prioritize non-opioid pain management as drugs or devices. I feel we are on the verge of groundbreaking work on pain.
  - Collins: Non addictive pain management is a priority. We have some human trials on nerve growth factor. We are trying to develop drugs for NAV 107. We are also examining congenital conditions creating an insensitivity to pain.

Rep. Barbara Lee (D-CA)

- I am concerned about the growing disparity of many medical conditions like Lupus and Alzheimer's among African-Americans. What is NIH doing to investigate the causes of growing health disparities?
  - Collins: We are looking at the root cause of these disparities and have many ongoing investigations into this topic.

Rep. Steve Womack (R-AR)

- The IDEA program awards research dollars to places like Arkansas to help them stay competitive. What are your plans on that program?
  - Collins: Our best research minds aren't all in big city universities. They are everywhere. We want to continue to provide federal resources to them.
- Would NIH consider hosting an interagency stakeholder summit on FDA-approved Medical Assisted Treatment for opioid addiction, and would you publish the findings of that summit?
  - Volkow: We agree with this idea and are moving forward on it. We need to educate communities on what they can already do. This would be very valuable.

Rep. Mark Pocan (D-WI)

- Of the 210 new drugs approved by the FDA last year, every single one was assisted by federal funding at some point in its research and development. Yet prescription drug costs continue to escalate. Is there something Congress can do to reduce prescription drug prices?
  - Collins: That is correct, NIH funding assisted at every stage for new therapeutics. But we cannot pull levers on drug prices or licensing. The reason drugs are so expensive is because the failure rate is so high. NCATS is designed to identify bottlenecks and speed them up.
- Classifying Kratom as a Schedule I drug can cause a mess.
  - Volkow: Kratom has properties of an analgesic. If it becomes Schedule I, all research will slow considerably.

Full committee Ranking Member Nita Lowey (D-NY):

- What is NIH doing to develop more early detection tools for cancer?
  - Sharpless: Early detection is a big part of our portfolio, especially for aggressive cancers. We are working on new radiological imaging, biomarkers in blood, and other novel approaches.
- I believe e-cigarettes are a gateway to harder drug use. Are e-cigarettes a public health threat for young people?
  - Volkow: It is a public health threat for young people. E-cigarettes are an area of great concern. We have been successful in reducing cigarette usage, but much of that has transferred to e-cigarettes.

Rep. Jaime Herrera Beutler (R-WA)

- An area of need in NIH is safe medication use during pregnancy. What is NIH doing?
  - Bianchi: We have assembled a task force and are developing recommendations to help pregnant mothers and lactating mothers better understand the health risks associated with various medications.
- Marijuana is becoming the biggest school safety problem in my district. What is NIH doing related to marijuana research?
  - Volkow: That is an area of concern for young people. Preliminary research suggests marijuana use can interfere with cognitive development, but there is no rigorous scientific review yet.

Rep. Katherine Clark (D-MA):

- What is NIH's plans regarding the Framingham heart study?
  - Collins: For 70 years NIH has looked at the hearts of this community and made major breakthroughs.

Rep. John Moolenaar (R-MI):

- The Helping to End Addiction Initiative is doing great work. How do we build on its work?
  - Collins: The institutes had a strategy retreat recently and all HHS agencies were involved. We must use our full infrastructure and communicate better with communities.