

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2014 Budget Request

Statement for the Record

Senate Subcommittee on Labor-HHS-Education Appropriations

Gary H. Gibbons, M.D.

Director, National Heart, Lung, and Blood Institute

May 2013

Mr. Chairman and distinguished members of the Subcommittee:

I am pleased to present the President's Budget request for the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). The fiscal year (FY) 2014 budget of \$3,098,508,000 includes an increase of \$25,206,000 over the comparable FY 2012 level of \$3,073,302,000.

NHLBI leads research and education programs to discover and apply knowledge to improve health by preventing and treating heart, lung, and blood diseases. It is a privilege to serve as NHLBI Director in this time of unprecedented opportunity in biomedical research. Today, I will discuss new opportunities to reduce health disparities, advance understanding of complex chronic diseases, and enhance clinical research.

HEALTH DISPARITIES RESEARCH

The NHLBI portfolio includes studies of many diseases that impose strikingly disparate burdens on Americans from different walks of life. Understanding and alleviating health disparities has been a passion of mine throughout my career, and I am honored to lead an Institute with such a longstanding commitment to supporting work in that area. Many of you are familiar with the NHLBI's large epidemiological studies that focus on minority populations, including the Jackson Heart Study in African Americans, the Hispanic Community Health Study, the Multi-Ethnic Study of Atherosclerosis, which includes a sizeable cohort of Asian Americans, and the Strong Heart study in American Indians. Our recent investments in genotyping of diverse cohorts promise to shed critical light on biological differences in disease susceptibility as well as the interactions between genes and environment as determinants of health among all

Americans. We also have an outstanding record of including substantial numbers of minorities in our clinical research, particularly in studies of high blood pressure, which appears with great frequency and often devastating complications in African Americans.

Efforts to date have yielded progress that has benefited most people to some extent but, unfortunately, has done little to close the gaps that persist between the healthiest and least healthy segments of society. Because health disparities are complex and are clearly influenced not only by genetics but also by factors such as family, social community, and physical environment, we believe that they offer an excellent model for a new “systems” approach to our research strategy. Until recently scientists have had to consider such factors separately; for instance, one researcher might look at basic biological pathways or genetic factors, while another examines lifestyle choices and a third considers socioeconomic influences. This piecemeal approach provides a limited view of how disease occurs and, more important, how it can be prevented or managed effectively. To revolutionize our understanding of health and disease, we are now developing and exploiting new tools that enable consideration of many factors—biological, behavioral, environmental—together in a holistic way. That, I believe, is the path to future progress in preventing and pre-empting chronic heart, lung, and blood disorders. If we can develop the “systems” research model for health disparities research we can transform both science and medicine by applying it more broadly to other public health needs.

A NEW PARADIGM FOR UNDERSTANDING COMPLEX DISEASES

Let me give you one example of recent findings that highlight the value of a cross-disciplinary approach. We have known for decades that the foods we eat influence our risk of developing cardiovascular disease (CVD). Observational studies have taught us the value of so-called heart-healthy diets that emphasize fruits, vegetables, whole grains, fish, and “good” fats such as olive oil. Nevertheless, controversies persist about the potential harmful effects of red meat consumption. Scientists still don’t know why certain foods increase or reduce the risk of CVD.

Recently, a provocative series of NHLBI-funded studies provided some important new insights into the potential link between red meat consumption and atherosclerotic CVD. Researchers have shown that the bacteria that reside in our guts and metabolize L-carnitine, a substance found in red meat, may be an important culprit behind CVD. This interaction between diet and gut microbes leads to the production of TMAO (trimethylamine-N-oxide), an organic compound that circulates in the blood and promotes the “clogging of arteries” by inhibiting the removal of cholesterol from atherosclerotic plaque.

This and other work is dramatically enhancing our view of how the trillions of microbes that co-exist in and around our bodies contribute to both health and disease. The research perfectly illustrates a “systems” approach that iteratively integrates studies in mice as well as large-scale population science and smaller-scale human studies. It provides an entirely new and critical understanding of the dynamic interplay between the factors that predispose patients to CVD.

ENHANCING CLINICAL RESEARCH

As we work to integrate our research efforts across multiple disciplines, we are placing particular emphasis on ensuring that our clinical research is robust. A major challenge is to enhance clinical trials, which provide critical evaluation of new preventive and therapeutic approaches but are, arguably, some of our most challenging and expensive undertakings. In recent years, the NHLBI has been exploring ways to make trials more efficient and more applicable to real-world clinical settings. Moving forward, we plan to build on past successes while capitalizing on new technologies and data sources, such as electronic medical records.

For many years, the NHLBI has used a network model to increase the efficiency of clinical trials. Our networks have a strong track record of conducting multiple, multi-center, clinical trials using standardized operations and sustainable infrastructures that minimize the time required to start new studies. They span a wide range of topics, such as asthma, cardiovascular cell therapy, pediatric heart disease, heart failure, childhood obesity, and transfusion medicine. A major problem facing our healthcare system is the costly cycle of chronic disease care that is characterized by persistent debilitating symptoms, hospitalizations for acute exacerbations of the condition, eventual hospital discharge, and then subsequent re-hospitalizations. To address this clinical practice challenge, the NHLBI is supporting innovation in discovery science that holds promise for breaking this vicious cycle of chronic heart, lung, and blood disorders. In 2014, we will pilot a new network structure to evaluate treatment strategies for acute, serious lung conditions—such as exacerbations of chronic obstructive pulmonary disease—that

require hospitalization. If the new model proves successful we will apply it to clinical trials of other chronic diseases that are treated in inpatient clinical settings.

Another cost-effective strategy that the NHLBI has used very successfully is funding ancillary studies piggybacked onto trials to maximize return on investment. For example an NHLBI-funded clinical trial demonstrating that aspirin reduces the risk of heart attack also included ancillary studies that sought to identify new risk factors for CVD. These ancillary discovery science projects superimposed on the original clinical trial yielded strong evidence that elevated levels of a marker for inflammation called c-reactive protein are correlated with CVD events. The insights gained from the original clinical trial and subsequent ancillary studies have led to an innovative strategy to reduce CVD that targets the inflammatory process as a causative factor in heart attacks. Accordingly, the NHLBI recently funded the Cardiovascular Inflammation Reduction Trial to determine whether treatment with the anti-inflammation drug methotrexate, which is commonly prescribed for rheumatoid arthritis, reduces the risk of heart attacks and strokes. Taken together, these studies illustrate the NHLBI's ongoing efforts to enhance the efficiency and return-on-investment of our clinical trial portfolio so that advances in the practice of medicine are translated into healthier lives for all Americans.

We also are pursuing new opportunities to conduct trials that are bigger, but simpler, with clinically relevant end points that leverage routine medical care and existing data in electronic medical records and registries. By using electronic health records data from real-world clinical practice, we hope not only to make trials more relevant to clinical practice, but also to make the results more robust and reproducible

by including hundreds of thousands of participants. In FY 2014, the Institute will explore the use of electronic medical records in clinical trials through a new initiative to compare the ability of two data sources, electronic health records and traditional prospective patient-based clinical and research data, to answer research questions about pediatric pulmonary vascular diseases. We anticipate that these innovations that enhance the cost-effectiveness of NHLBI's approach to supporting clinical research will yield additional new discoveries that have a dramatic impact on the health outcomes of patients with chronic heart, lung, and blood disorders.

Gary H. Gibbons, M.D.

Director, National Heart, Lung and Blood Institute

Gary H. Gibbons, M.D., is Director of the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH), where he oversees the third largest institute at the NIH, with an annual budget of approximately \$3 billion and a staff of 1,000 federal employees.

NHLBI provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

Prior to being named director of the NHLBI, Dr. Gibbons served as a member of the National Heart, Lung, and Blood Advisory Council (NHLBAC) from 2009-2012. He was also a member of the NHLBI Board of Extramural Experts (BEE), a working group of the NHLBAC.

Before joining NHLBI, Dr. Gibbons served as the founding director of the Cardiovascular Research Institute, chairperson of the Department of Physiology, and professor of physiology and medicine at the Morehouse School of Medicine, in Atlanta.

Under his leadership of the Cardiovascular Research Institute, Dr. Gibbons directed NIH-funded research in the fields of vascular biology, genomic medicine, and the pathogenesis of vascular diseases. During his tenure, the Cardiovascular Research Institute emerged as a center of excellence, leading the way in discoveries related to the cardiovascular health of minority populations. Dr. Gibbons received several patents for innovations derived from his research in the fields of vascular biology and the pathogenesis of vascular diseases.

Dr. Gibbons earned his undergraduate degree from Princeton University in Princeton, N.J., and graduated *magna cum laude* from Harvard Medical School in Boston. He completed his residency and cardiology fellowship at the Harvard-affiliated Brigham and Women's Hospital in Boston. Prior to joining the Morehouse School of Medicine in 1999, Dr. Gibbons was a member of the faculty at Stanford University in Stanford, Calif., from 1990-1996, and at Harvard Medical School from 1996-1999. Throughout his career, Dr. Gibbons has received numerous honors, including election to the Institute of Medicine of the National Academies of Sciences; selection as a Robert Wood Johnson Foundation Minority Faculty Development Awardee; selection as a Pew Foundation Biomedical Scholar; and recognition as an Established Investigator of the American Heart Association (AHA).