

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Implementation of ARRA

Witness appearing before the
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Good morning, Mr. Chairman and distinguished Members of the Subcommittee. It is an honor and a privilege to appear before you today to discuss the National Institutes of Health's (NIH's) implementation of the American Recovery and Reinvestment Act (ARRA).

First, I want to express our gratitude for your support for NIH in the FY 2009 budget, and for the continued trust that you place in NIH to make the discoveries that will lead to better health for everyone, as reflected in the recent appropriation of \$10.4 billion in ARRA and the 3.2% increase in the FY 2009 Appropriations Act.

I thank you on behalf of the many scientists we are able to support at more than 3,000 research institutions throughout the 50 states and U.S. territories; and on behalf of the public, who count on our research to help detect, treat, or prevent hundreds of diseases and conditions.

As you well know, research conducted and supported by the NIH touches people's lives every day. NIH is the largest single engine for outstanding biomedical research in this country—and the world. Not only does NIH have an impact globally, it also has a lasting impact at the community level, bringing intellectual and economic growth to towns and cities across America.

My testimony will be different from testimony that NIH presented in past years, because we are facing unique times. We are in one of the worst economic crises in American history—the worst in my lifetime. It is an unfortunate irony that it comes at the same time that we see great scientific opportunities for improving health. The biomedical research community is not spared from the drastic downturn in the economy. This is worrisome not only because it means fewer jobs, but also because innovation and a constant influx of young talent are crucial to the nation's economic success and a robust biomedical research enterprise.

So, it is timely that the President and Congress provided ARRA funds to the NIH to stimulate the economy and advance biomedical and behavioral research.

I'd like to share with you the following: One of our program directors received an email several days ago in response to news that an applicant's grant application is being considered for funding with ARRA money.

Here is an excerpt from the email (with names deleted):

“Forgot to say that we gave a termination letter last Friday to my longtime (5 years) postdoc. His job has been saved. He is going to be thrilled to hear about his change in fortune! I also would like to hire a technician with the new funds, since at present I do not have one.”

We are moving expeditiously to identify the best science and support it with the additional \$10.4 billion provided by ARRA to the NIH, and obligate it within the next two years. Moreover, your decision sends a strong signal to the scientists in the field, and to bright young people who may one day choose science as a career, that the United States is working to support outstanding research and outstanding scientists.

Let me highlight some of the important work that we will support with ARRA funds. For example, we will rapidly expand our current understanding of the genetic changes associated with a wide range of diseases and conditions, including addiction, Alzheimer's disease, various forms of cancer, chronic pain, diabetes, glaucoma, heart and lung diseases, kidney disease, and mental disorders, through genetic analysis of existing, well characterized population cohorts. We will take steps toward using this genetic information to better inform the modification of disease for those patients most at risk, principally through life-style factors and personal health behaviors.

In addition, our efforts to expand community-based research efforts, with special focus on minority and underserved patients, will be accelerated through catalytic grants designed to enhance interrelationships among academic health centers, community organizations, and community health care clinical centers. Evaluation of the health and safety risks of nanoscale products is critical as nanomaterials are being used in

applications as diverse as medical devices, drug delivery, cosmetics, and textiles. Biological, physical, and chemical characterization of selected nanomaterials will be conducted to both inform the establishment of standards for health and safety and developing computational models for the prediction of long term secondary effects.

Just to review briefly, the ARRA provided NIH funding in the following ways:

- It allocated \$1.3 billion for the National Center for Research Resources, with \$1 billion identified for extramural construction and renovation, and \$300 million targeted for shared instrumentation and other large capital research equipment. The positive impact of this support for institutions and researchers will be extraordinary, providing broader access to state-of-the-art equipment. Funding for extramural construction and renovation will result in jobs in construction and a number of trades in the building industry. Shared instrumentation will improve the quality and even the speed of the work that is done, and build collaboration in ways that will accelerate discovery. Shared instrumentation, including such resources as advanced real-time imaging tools, will allow scientists to image the brain in action or enable them to see separate proteins that play a role in health and disease.
- It appropriated \$8.2 billion to NIH, of which \$7.4 billion will be distributed through the NIH Office of the Director, to the Institutes and Centers of NIH, and to the Common Fund for the support of biomedical research. The remaining \$800 million will be distributed by the Office of the Director to fund specific challenges and scientific priorities at the Institutes and Centers.
- In addition, \$400 million transferred to NIH by the Agency for Healthcare Research and Quality (AHRQ), as directed under ARRA, will be used to support comparative effectiveness research.

- The remaining \$500 million will be used to fund high priority repairs, improvements, and construction on the NIH campus to enable the highest quality research to be conducted.

How will NIH accomplish this task?

NIH is determined to seize the opportunity afforded us by the infusion of ARRA resources to develop a nimble approach to investing the money quickly with the greatest impact. This opportunity is too important for us to conduct “business as usual.” It demands that we employ the best possible approaches to ensure progress in an accelerated time, with the most efficient and effective use of resources. For example, we are scrutinizing the 14,000 grant applications we received in our last round of review—applications that were already deemed highly meritorious and approved by Advisory Councils at each Institute and Center—applications that, despite their merit, we could not fund before. We are now identifying and planning to fund those scientifically meritorious applications for two years, where the scientific plan is appropriate for a 2-year award instead of the usual 4-year award. Also, every Institute and Center is identifying scientific priorities that can be funded through administrative supplements. Administrative supplements will allow for accelerating the progress of a promising grant, typically by adding support for postdoctoral scientists and graduate students and key pieces of equipment.

The NIH team is proud of the trust placed in it to be a part of the economic recovery process. NIH will work tirelessly to support the goals and intent of ARRA, with wise resource investments in science. Several new funding announcements have already been released. In fact, in the first week after enactment of ARRA, NIH announced requests for applications of \$1.5 billion.

NIH has created a number of new programs that will spur new areas of research and trigger an almost immediate influx of research dollars into communities across the nation. For example, NIH created a new program called the Challenge Grant award. To kick start

this program, we issued the largest Request for Applications in our history. This 220-page document lists numerous scientific topics in fifteen broad scientific areas, including: bioethics, translational science, genomics, health disparities, enhancing clinical trials, behavioral change and prevention, and regenerative medicine—areas that would benefit from a jumpstart or in which a scientific challenge needs to be overcome. We expect to devote at least \$200 million of these funds to this effort.

I will highlight only a few examples of the Challenge Grant topics that could be further explored:

- New advances in biosensors and lab-on-chip technology to create novel ways to measure the body burden and sub-clinical health effects of emerging contaminants in the environment in large study populations. Additional research funds could support field testing of the most promising sensors and analysis techniques through collaboration with existing epidemiologic studies taking advantage of both new and banked tissue specimens.
- There is increasing evidence that suggests that HIV-1 infected individuals experience similar immunologic changes as the uninfected elderly. This may be due to persistent stimulation of the immune cells. It is not clear whether antiretroviral therapy can reverse this process. Research will aim to compare the effectiveness of different treatment regimens in reversing or preventing accelerated aging that appears in the immune and other body systems.
- Studies are needed to assess the impact and ethical considerations of conducting biomedical and clinical research internationally in resource-limited countries.
- Studies on ethical issues in health disparities and access to participation in research is needed to assess the under-representation in biomedical and clinical research of U.S. minority populations, underserved populations, and populations who may be vulnerable to coercion or undue influence; and to identify barriers to participation in research and to develop approaches for overcoming them.

- Pain research has been greatly hampered by the unreliable nature of self-report based instruments, where we rely on the person in pain to tell us about their condition, which can be highly subjective. The establishment of objective, affordable and reliable pain biomarkers and measurements would advance our understanding of pain mechanisms, provide a basis for improved clinical management of pain, help assess an individual's risk for becoming addicted to opiate analgesics, and establish much needed objective measures of treatment success or failure.
- Development of novel approaches for delivering combined diagnostic and therapeutic agents to appropriate disease sites with high specificity and in adequate concentrations to realize the promise of combined diagnosis and treatment of diseases in a single sitting, hence the hybrid term, “theranostics.”

Another new program is what we call the Grand Opportunity Program, or “GO grants.” The purpose of this program is to support high impact ideas that require significant resources for a discrete period of time to lay the foundation for new fields of investigation. The GO program will support large-scale research projects that accelerate critical breakthroughs, early and applied research on cutting-edge technologies, and new approaches to improve the synergy and interactions among multidisciplinary and interdisciplinary research teams. Applicants may propose to address either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress. For those projects that span the missions of multiple Institutes, Centers and Offices (ICs), support may come from ARRA funds allocated to the Common Fund.

NIH will identify a number of Signature Initiatives that will support exceptionally creative and innovative projects and programs—and potentially transformative approaches to major challenges in biomedical research. The initiatives will cover new scientific opportunities in nanotechnology, genome-wide association studies, health

disparities, arthritis, diabetes, autism, the genetic risk for Alzheimer's disease, regenerative medicine, oral fluids as biomarkers, and HIV vaccine research.

Each IC is developing at least one Signature Initiative, and a number will be done in partnership across ICs and/or the Office of the NIH Director. The areas being developed include an Office of the Director-led set of catalytic awards to enhance community-based research efforts to ensure that we are able to reach segments of our Nation that are too often overlooked in clinical research.

In addition, considerable investment is expected to be made to understand the genetics of a wide range of specific diseases and conditions, as well as second generation "deep DNA sequencing" of very large and well-defined national patient cohorts to identify disease causing genetic variants that may express at low frequencies but cause greater effect. An initiative to modify disease risk based on genome-wide association findings is also being planned. Complementing this will be initiatives to accelerate biomarker discovery and validation.

Also, NIH will use other funding mechanisms, such as the Academic Research Enhancement Award, or AREA grants, that support small research projects in the biomedical and behavioral sciences conducted by faculty and students in health professional schools and other academic components that have not been major recipients of NIH research grant funds. A research program to support new faculty, called the "Core Centers for Enhancing Research Capacity in U.S. Academic Institutions," will address the need for more bioethicists and provide opportunities for young scientists, who are one of NIH's top priorities for support. The Core Center grants are designed to establish innovative programs of excellence by providing scientific and programmatic support for research by promising investigators. They provide funding to hire, provide appropriate start-up packages, and develop pilot research projects for newly-independent investigators, with the goal of augmenting and expanding the institution's biomedical research base. We must invest today to ensure tomorrow's scientific discoveries.

ARRA Funds for Administrative Supplements

U.S. institutions and investigators with active NIH research grants may request administrative supplements for the purpose of accelerating the pace of scientific research through the programs and activities of their peer-reviewed projects. These supplements seek to promote job creation and retention, as well as scientific progress at NIH-funded institutions, by providing researchers with the means to employ, for example, post-graduate students or to enhance capacity for data analysis.

We are particularly delighted to tell you about our expanded summer program for teachers and students across America. Funds will provide short-term summer jobs for high school and undergraduate students—as well as elementary, middle, high school and community college science educators in laboratories around the country—work that will not only provide summer income, but will also provide several thousand young people with the opportunity to experience the world of research, and I hope will spark their desire to become scientists.

In addition to administrative supplements, U.S. research institutions and scientists with active NIH Research Grants may submit revision applications (so-called “competitive supplements”) to support a significant expansion of the scope or research protocol of currently approved and funded projects.

The Economic Benefits

We are mindful that a top priority for the use of ARRA funds by NIH is to create and preserve jobs, as well as increase purchasing power in all corners of the country. We firmly believe that we can do this while carrying out the core NIH mission, and without compromising our commitment to fund the best scientific research ideas. In keeping with the ARRA reporting requirements, we are asking recipients to document key economic benefits, such as jobs created and retained. A study indicates that, on average, every NIH grant supports 6 to 7 in-part or full scientific jobs.¹ Another study suggests that every

dollar spent by NIH in local communities around the Nation is leveraged on average three times its original amount, if you look at the national “economic multiplier” effect.² These grants pay the salaries of scientists and technicians. The scientists and technicians, in turn, purchase goods and services in the communities in which they work and live.

ARRA: RISK MANAGEMENT

NIH has implemented a risk management program in compliance with OMB guidelines that addresses the identification and assessment of proper controls over financial reporting and operations processes. In the financial arena, the risk program includes reviews of financial reporting at the transaction level that are conducted by both internal and external auditors. In the operations arena, the program includes internal assessments of systems and processes that support both intramural and extramural research.

Under ARRA, the existing framework will be leveraged to document and track projects and activities receiving ARRA funding taking into consideration all additional controls, tests and reports that are called for in the Act and the implementing OMB and HHS guidelines. NIH is working with the Department’s Office of Inspector General to facilitate their responsibilities under the Act and to partner, where practical and appropriate, in oversight, review and testing of internal controls pertaining to ARRA funds.

The Scientific Benefits

The advancement of science is a gradual process. Groundbreaking discoveries are most often built on the foundation of many gradual advances that bring us closer to diagnosis, treatments, and other public health improvements expected by Congress and the American public. Because of ARRA funds, there may be many such discoveries across the country next year and many years thereafter. These discoveries could yield better understanding of the major diseases and disorders such as heart disease, cancer,

neurodegenerative illnesses, autism, arthritis, mental health, chronic, acute and rare diseases, and diseases related to addiction or behavior.

We are committed to ensuring that ARRA funds will produce benefits to the economy, to scientific knowledge, and ultimately aid in improving the health of the Nation. As an agency, we are well-equipped to disburse these resources, to handle the increase in workload, and award grants expeditiously to the best scientists in the world.

In the very near future, the President will present the FY 2010 budget request. Our FY 2010 budget will reflect the President's emphasis on increasing research in the areas of cancer and autism, to which we know Congress has shown great attention as well. We look forward to working with the Committee to enact the FY 2010 budget request.

Before concluding, I want to update you on several adjustments and mid-course corrections we are making to the National Children's Study (NCS).

As you know, the NCS is in the early pilot stages and is envisioned as a long-term study to follow children from birth through their teenage years. These studies have a number of factors, assumptions, and estimates. We are actively working to manage this program. Earlier this year, we learned that, if all the potential components of the study were to actually go forward, the most recent total estimate would not be within the spending range expected by the agency.

Studies of this nature and length have cost uncertainty. We strive hard to manage these uncertainties. The NCS is truly of unprecedented size and scope. Once I learned of the potential cost variance, I took the following actions:

- o Increased oversight of decisions pertaining to the NCS.
- o A former senior NIH scientist, known for his scientific management expertise, was brought in to review the study and advise the NIH leadership on potential actions.

- o The NIH Office of Management Assessment initiated a review to ensure we learn from the process and improve study planning.
- o We have established a revised two-year plan to outline steps to assess true costs, review the study after the pilot, modify the study to balance science and fiscal prudence as necessary, and apply rigorous scientific review to the final protocol. Final decisions are expected to be made in August 2010.

Once we complete the pilot review and examine the cost data and projects, we will work to ensure the study is fiscally and scientifically responsible; however, there will certainly be adjustments to the scope and/or scale of the study. I am hopeful that with increased oversight and adaptations, the study will go forward and yield important findings about the health of children.

As I said in my opening comments, we are grateful for your trust in NIH and your commitment to biomedical research and all the promise it brings to people here in the United States and around the world. We have employed a number of innovative strategies to quickly and wisely invest ARRA funds. We have also developed brand-new programs, such as the Challenge Grants, to help us do just that. We will provide you and the public with regular updates and reports to ensure full transparency and accountability for how these funds are being spent. Americans deserve to know the impact of their tax dollars—on science, on the economy, and the Nation's health.

I would be pleased to answer any questions that you might have.

***** Footnotes/Citations *****

1. "Estimating the Number of Senior/Key Personnel Engaged in NIH Supported Research," study issued October 2008. Study funded by the NIH Evaluation Set-Aside Program, 07-5002-OD-ORIS-OER, administered by the Evaluation Branch, Division of Evaluation and Systematic Assessment, OPASI, Office of the Director, National Institutes of Health.

2. “In Your Own Backyard: How NIH Funding Helps Your State’s Economy,”
published by Family USA (A Global Health Initiative Report). June 2008.

Dr. Raynard S. Kington, M.D., PhD

Dr. Raynard S. Kington, M.D., PhD. was named Acting NIH Director of the National Institutes of Health on October 31, 2008, following the departure of Dr. Elias A. Zerhouni, M.D. Since February 9, 2003, when Dr. Kington was appointed Deputy Director of the National Institutes of Health (NIH), he shared in the overall leadership, policy direction, and coordination of NIH biomedical research and research training programs of NIH's 27 Institutes and Centers with a budget of almost \$29 billion and 18,000 employees.

Prior to this appointment, he had been Associate Director of NIH for Behavioral and Social Sciences Research since September, 2000. In addition to this role, from January, 2002 to November, 2002, he served as Acting Director of the National Institute on Alcohol Abuse and Alcoholism.

Prior to coming to NIH, Dr. Kington was Director of the Division of Health Examination Statistics at the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). As Division Director, he also served as Director of the National Health and Nutrition Examination Survey (NHANES), one of the nation's largest studies to assess the health of the American people.

Prior to coming to NCHS, he was a Senior Scientist in the Health Program at the RAND Corporation. While at RAND, Dr. Kington was a Co-Director of the Drew/RAND Center on Health and Aging, a National Institute on Aging Exploratory Minority Aging Center.

Dr. Kington attended the University of Michigan, where he received his B.S. with distinction and his M.D. He subsequently completed his residency in Internal Medicine at Michael Reese Medical Center in Chicago.

He was then appointed a Robert Wood Johnson Clinical Scholar at the University of Pennsylvania. While at the University of Pennsylvania, he completed his M.B.A. with distinction and his Ph.D. with a concentration in Health Policy and Economics at the Wharton School and was awarded a Fontaine Fellowship. He is board-certified in Internal Medicine and Public Health and Preventive Medicine.

In 2006, Dr. Kington was elected to membership in the Institute of Medicine of the National Academy of Sciences. Dr. Kington's research has focused on the role of social factors, especially socioeconomic status, as determinants of health.

His research has included studies of the health and socioeconomic status of black immigrants, demographic correlates of the willingness to participate in genetic research, the relationship between wealth and health status, the health status of U.S. Hispanic populations, and the determinants of health care services utilization.