



## FRIENDS OF THE NATIONAL INSTITUTE ON AGING

A broad-based coalition of aging, disease, research, and patient groups supporting the mission of the National Institute on Aging (NIA).

February 10, 2015

The Honorable Fred Upton  
Chairman  
U.S. House of Representatives  
Committee on Energy and Commerce  
2368 Rayburn House Office Building  
Washington, DC 20515

The Honorable Diana DeGette  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Representative DeGette,

The Friends of the National Institute on Aging (FoNIA), [www.friendsofnia.org](http://www.friendsofnia.org), is a coalition of more than 50 academic, patient-centered and non-profit organizations that supports the research and training missions of the National Institute on Aging (NIA) by promoting and advocating for the NIA and its initiatives as public policies in health and research take shape. We applaud your interest in accelerating the development of treatments, particularly for diseases and populations with high unmet need. The discussion draft may help in some ways, however there are select provisions in the bill that we would suggest revising so that they may better serve the needs of our aging population.

### **TITLE II- BUILDING THE FOUNDATION FOR 21<sup>ST</sup> CENTURY MEDICINE, INCLUDING HELPING YOUNG SCIENTISTS**

#### **Subtitle N-21<sup>st</sup> Century Chronic Disease Initiative Act**

We recommend that the proposal not include a new, traditional longitudinal study—including the development of a plan to carry out such a study, or an actual study. A new study would be redundant to existing similar projects, would risk diverting scarce resources (capital, researchers and study participants) from other chronic disease research, and—with regard to Alzheimer’s disease in particular—would be too slow relative to the established national goal of preventing and effectively treating Alzheimer’s by 2025. A variety of longitudinal studies in Alzheimer’s and other chronic disease already are underway, some for 20 years or more. Existing studies are gathering demographic, social, behavioral, biological, health, and genetic data about their participants. These studies represent decades of thoughtful investment and scientific design, demonstrating the value of large representative cohorts and the incorporation of measurements of early life, behavioral, social, and economic factors with genetic and biological data to understand complex diseases.

#### **Subtitle O-Helping Young Emerging Scientists**

We recognize the many reports about early-career, American researchers that are fleeing the lab to pursue more stable careers overseas or new professions altogether. Sections 2261-2262 proposes to redirect funds from the Public Health Service Evaluation Set-Aside, known informally as the

“evaluation tap,” that totals about \$700 million per year, back to the National Institutes of Health (NIH) to support grants for emerging scientists as a way to spur medical innovation.

FoNIA agrees that it is important to fund young scientists in all research disciplines. However, if these provisions were to pass, it would have severe, unintended consequences for health research and public health.

The evaluation tap was established in 1970 to fund cross-cutting and evaluative activities of the Department of Health and Human Services (HHS). In this capacity, the evaluation tap funds several agencies and their research, program evaluation, and data collection activities—each of which is critical to assessing and improving health. For example:

- The **Agency for Healthcare Research and Quality (AHRQ)** supports data collection and research activities to improve health care. Such evidence informs efforts to make health care safer, higher quality, and more accessible, equitable, and affordable. *AHRQ’s appropriated budget is fully funded by the evaluation tap.*
- The **National Center for Health Statistics (NCHS)** at the Centers for Disease Control and Prevention (CDC) provides critical data on all aspects of our health—infant mortality and causes of death, chronic disease prevalence, emergency room use, rates of insurance, and teen pregnancy, to name a few. These data are used extensively in health research by NIH-funded scientists, among others. *More than half of NCHS’s appropriated budget is supported through the evaluation tap.*
- CDC’s **National Immunization Survey** is an essential tool for monitoring immunization coverage rates and identifying and reaching populations at greatest risk for vaccine-preventable diseases. The data collected through this survey drive CDC’s \$560 million immunization program. *The National Immunization Survey is fully funded by the evaluation tap.*
- The **National Library of Medicine**, CDC’s **National Institute for Occupational Safety and Health (NIOSH)**, and evaluative projects designed to assess the performance of federal programs across HHS are *wholly or partially funded by the evaluation tap.*

In the absence of appropriated funding for these currently “tap-funded” programs—the use of NIH’s evaluation tap funds for grants for early-career scientists would ultimately come at the expense of many important programs designed to increase understanding and improve Americans’ health and well-being. It is for this reason that FoNIA supports removing these provisions from the bill.

## **TITLE IV- ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21<sup>ST</sup> CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS**

### **Subtitle A -National Institutes of Health**

#### **Section 4001—NIH research strategic investment plan**

This section would require the Director of the NIH to develop a “5-year biomedical research strategic investment plan” to make funding allocation decisions, including strategic investment for each institute; have a common format; and identify strategic focus areas. While FoNIA does not oppose the creation of an agency-wide biomedical research investment strategic plan, we believe that Congress should not be in the business of dictating the well-established peer-review process for choosing research awards. Therefore, FoNIA strongly supports the removal of “(A) Funding Priority for NIH Overall.—In developing and maintaining a strategic investment plan under this

subsection, the Director of NIH shall ensure that at least 55 percent of the funds that are used by the National Institutes of Health to support extramural research for any fiscal year are used to support basic biomedical extramural research.”

Extramural grants in particular represent more than 80% of the \$31.2 billion NIH budget. Through its approximately 1,200 individuals and \$112 million budget, the Office of Extramural Research (OER) provides the infrastructure that makes these grants happen. OER provides the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH research grant portfolio with the ultimate goal of preserving public trust in research. A peer review system that includes scientists, physicians, and other experienced individuals in biomedical fields from around the world evaluate the merit of proposed research and its potential to advance science.

It should be noted that, currently, the 27 individual institutes and centers (ICs) at the National Institutes of Health (NIH) set their own research priorities, and they already do so with relative consistency. An [April 2014 GAO study](#) found that the five selected ICs—awarding the largest amount of research funding—that it reviewed did so considering similar factors and using various priority-setting approaches. Agency officials stated that the ICs' mission and appropriations inform priority-setting approaches. In priority setting, IC officials reported taking into consideration scientific needs and opportunities, gaps in funded research, the burden of disease in a population, and public health need, such as an emerging public health threat like influenza that needs to be addressed. While each IC GAO examined had its own approach for setting priorities, they all considered the input of stakeholders, including the scientific community, and used some similar strategies. All five ICs also conducted reviews and evaluations of their research portfolios to ensure that their priorities align with scientific opportunities, research gaps, and emerging science. In addition to these efforts at the IC level, agency officials told GAO that the NIH Office of the Director provides leadership and coordinates priority setting activities, especially for those activities that involve multiple ICs.

#### **Section 4004—increasing accountability at the National Institutes of Health**

This section would create a four-year term for each institute and center director at the National Institutes of Health. FoNIA opposes this provision and supports its removal.

Currently, the Directorships of NIH Institutes and Centers (i.e., other than that of the NCI, which is appointed by the President under the 1971 National Cancer Act) are filled by the NIH Director and 1) do not require a Presidential Appointment or Congressional Approval and 2) do not have terms for their appointment. We believe that the introduction of terms will distract Directors with campaigning and will encourage jockeying among colleagues who should be spending their time on managing research programs. The NIH Director is already allowed to hire and fire, and IC Directors positions should not be further politicized.

Additionally, FoNIA opposes the requirement for IC Directors to review R-series Grants to determine “whether the goals of the research program or project are a national priority and have public support.” Not only is this requirement completely subjective and impossible to prove either way, but it is also the stuff of political campaigns, not science, and should not be used to award federal funding for research.

Chairman Upton and Congresswoman DeGette, thank you for your leadership on behalf of patients and your careful consideration of the views expressed above. We hope the committee will contemplate the suggested modifications when it releases its next draft and moves forward with legislative action on 21<sup>st</sup> Century Cures. If you have any questions or would like additional information, please do not hesitate to contact Susan Peschin, MHS, Chair of FoNIA, at (202) 293-2856, or email [speschin@agingresearch.org](mailto:speschin@agingresearch.org); or Kathy Jedrziwski, Ph.D., co-Chair of FoNIA, at (215) 898-2445 or email [jedrzmk@mail.med.upenn.edu](mailto:jedrzmk@mail.med.upenn.edu).

Sincerely,

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