

July 6, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The undersigned members of the Ad Hoc Group for Medical Research, representing patient groups, scientific societies, research institutions, and industry, commend you for your leadership and vision undertaking a bipartisan initiative to examine the process for getting safe treatments, devices, and cures to patients and the critical role of the National Institutes of Health (NIH) in that process. As your committee begins to draft legislation to implement recommendations to enhance the role of NIH, we are pleased to offer the following recommendations, which represent the consensus of the undersigned organizations and institutions.

Stabilize the NIH Budget Through Sustained Increases in Appropriations – As your committee’s hearings have helped document, we are in a time of unprecedented scientific opportunities and pressing health needs. If we are to achieve the full potential of advances in areas such as precision medicine, neuroscience, digital health technologies, and the other emerging opportunities discussed by your committee, the NIH budget will require sustained, predictable real growth. As you know, the NIH budget has lost nearly 25 percent of its purchasing power since 2003 after adjusting for inflation.

We believe that increases in appropriations of at least 5 percent annually for the next five years would enable thoughtful planning and efficient use of funding. This is similar to the recommendations of the American Academy of Arts and Sciences in its 2014 report “Restoring the Foundation: The Vital Role of Research in Preserving the American Dream.”

Affirm Existing NIH Support for Interdisciplinary Scientific Research – The NIH is authorized to stimulate and support research from basic through the full spectrum of translational, including biomedical, social, behavioral, and health services research. The HELP Committee legislation should reaffirm, rather than narrow, the agency’s existing mandate to support interdisciplinary science and the full spectrum of scientific disciplines.

Grant NIH “Carry-Over” Budget Authority – Because of its one-year budget cycle, compounded by delays in passage of appropriations bills, NIH forfeits a portion of its budget every year. Moreover, the compressed funding cycle creates administrative obstacles for NIH and the extramural community. Other federal research agencies with the ability to carry over funding into the next fiscal year include the National Science Foundation, the Department of Veteran Affairs Medical and Prosthetic Research Program, and the Department of Energy Office of Science.

Ease the Burdensome Travel Restrictions for Federal Researchers – Ideally, this would be accomplished by exempting federal employee attendance at scientific and technical meetings and conferences from the policies included in Office of Management and Budget (OMB) Memorandum M-12-12. Similar language was included in the text of the draft FY 2015 Senate Labor-HHS Appropriations bill [Sec. 526. (b)].

Address Regulatory Burden – We thank you for your interest in reducing the administrative burden for researchers and institutions, and we share your concern that regulatory burden takes valuable time away from research. We recommend that several steps be taken to reduce administrative burden:

- **Human Subject Protection** – We suggest that Institutional Review Boards (IRB) regulations be tied to risk, exempting certain categories for research and allowing minimal risk protocols – such as public use data from health assessment surveys – to avoid continuing review. The community is awaiting final guidance from NIH on allowing single IRBs to suffice for multi-site studies and reducing the requirements for IRB documentation at the initial proposal stage. Further, greater harmonization between NIH’s human subject protection protocol and HHS’ protocol might reduce administrative time.
- **Financial Conflict of Interest Reporting** – We support the promotion of transparency, and we urge that the three-year review of the reporting requirements called for by the Public Health Service be conducted. Further, this review should include stakeholder meetings to examine ways to reduce this reporting burden without decreasing the effectiveness of conflict of interest reporting.
- **Administrative Burden Is Not Limited to NIH Grants** – In particular, two requirements from OMB are burdensome and duplicative: effort reporting and subrecipient monitoring.

Effort reporting per OMB Circular A-21 requires faculty to regularly identify and certify the amount of time that they and their staff, including unpaid

volunteers, expend on individual research grants. The National Science Board's 2014 report "Reducing Investigators' Administrative Workload for Federally Funded Research" suggested that institutions' payroll systems could provide automated time and effort information that could be certified to fulfill effort reporting. We support that recommendation.

Requiring primary grant awardees to monitor subrecipients of grants for compliance is duplicative in the many instances that subrecipients receive federal funds and must already file compliance documentation.

Again, the community thanks you for your leadership in sustaining NIH as a national priority, and we look forward to working with you and your committee as you move forward in drafting legislation.

Sincerely,

AcademyHealth

Academy of Radiology Research

Alpha-1 Foundation

American Academy of Pediatrics

American Anthropological Association

American Association for Cancer Research

American Association for Dental Research

American Association for the Study of Liver Diseases

American Association of Colleges of Nursing

American Association of Colleges of Osteopathic Medicine

American Association of Colleges of Pharmacy

American Association of Immunologists

American Association of Neurological Surgeons

American Association of Neuromuscular and Electrodiagnostic Medicine

American Brain Coalition

American Cancer Society Cancer Action Network

American Chemical Society

American College of Rheumatology

American Educational Research Association

American Institute for Medical and Biological Engineering

American Liver Foundation

American Pediatric Society

American Physiological Society

American Psychological Association

American Society for Biochemistry and Molecular Biology

American Society for Microbiology

American Society for Pharmacology and Experimental Therapeutics (ASPET)

American Society for Reproductive Medicine

American Society of Clinical Oncology

American Society of Hematology

American Society of Nephrology
American Society of Transplantation (AST)
American Sociological Association
American Thoracic Society
American Veterinary Medical Association
Association for Clinical and Translational Science
Association of Academic Health Sciences Libraries (AAHSL)
Association of Academic Physiatrists
Association of American Cancer Institutes
Association of American Geographers
Association of American Medical Colleges
Association of American Universities
Association of American Veterinary Medical Colleges
Association of Independent Research Institutes
Association of Medical School Pediatric Department Chairs
Association of Public and Land-grant Universities
AVAC
Biophysical Society
Clinical Research Forum
Coalition for Imaging and Bioengineering Research
Coalition for the Life Sciences
Congress of Neurological Surgeons
Consortium of Social Science Associations (COSSA)
The COPD Foundation
Council on Governmental Relations
Crohn's and Colitis Foundation of America
Cystic Fibrosis Foundation
Digestive Disease National Coalition
Federation of American Societies for Experimental Biology
Federation of Associations in Behavioral and Brain Sciences
GBS/CIDP Foundation International
Genetics Society of America
Harvard University
Hepatitis B Foundation
HIV Medicine Association
Infectious Diseases Society of America
International Foundation for Functional Gastrointestinal Disorders
Lupus Foundation of America
The Marfan Foundation
Medical Library Association (MLA)
Mesothelioma Applied Research Foundation
National Alliance for Eye and Vision Research (NAEVR)
National Fragile X Foundation
National Multiple Sclerosis Society
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
Penn Medicine

Population Association of America and Association of Population Centers
Pulmonary Hypertension Association
Michigan State University
Muscular Dystrophy Association
National Alliance for Eye and Vision Research
National Alopecia Areata Foundation
National Association for Biomedical Research
National Organization for Rare Disorders
Northeastern University
Northern Illinois University
NYU Langone Medical Center
Oregon Health & Science University
Scleroderma Foundation
Sleep Research Society
Society for Pediatric Research
Society for Women's Health Research
Society of General Internal Medicine
The Sturge-Weber Foundation
Unite 2 Fight Paralysis
University of Michigan
University of Pennsylvania
Vanderbilt University