

October 1, 2012

The Honorable Dennis Rehberg
Chair
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
United States House of Representatives
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
United States House of Representatives
Washington, DC 20515

Dear Chairman Rehberg and Ranking Member DeLauro:

As you craft the final appropriations bills for fiscal year (FY) 2013, the undersigned organizations and institutions, which represent patients, scientists, health care providers, and industry, wish to express their concerns about provisions for the National Institutes of Health (NIH) included in the bill adopted by the House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies (LHHS) on July 18.

Although we recognize the difficult fiscal decisions facing Congress in these economically challenging times, we believe the funding level provided for NIH in the legislation falls short of what is needed to ensure U.S. global competitiveness in medical research and advance critical scientific discoveries that improve human health. In addition to failing to provide the level of investment in NIH needed to improve the health of the nation, reduce human suffering, and protect the country against new and emerging disease threats, the bill includes a number of policy provisions that, if implemented, would undermine NIH's ability to support the best science.

The extraordinary improvements in health that have resulted from NIH-funded research are a credit to the efficient and competitive award system that is the envy of the world. NIH Institutes and Centers have the flexibility to make the type and size of awards that are best suited to meet current health challenges and utilize scientific opportunities. If NIH is to continue to fund the highest quality research and the next generation of talented researchers in the most effective manner possible, Congress should not tie the hands of the agency by setting arbitrary boundaries on the number and size of awards.

Many of the bill's other policy provisions over-regulate NIH and may inadvertently impede the agency's ongoing efforts to improve the stewardship of its resources. We do not support the arbitrary ratio of extramural to intramural research funding. While we appreciate the

subcommittee's strong endorsement of the extramural research community, NIH should make decisions on allocating resources to research activities supported by the agency based on the best available science and current health challenges.

The legislation prescribes the number of training awards that NIH should fund in FY 2013, potentially undermining NIH's efforts to address issues raised in the recently released and long-awaited report of the Advisory Committee to the NIH Director Working Group on the Biomedical Research Workforce.

We also object to the proposal to lower the extramural salary cap to Executive Level III. Universities and medical schools have already had to divert funds to compensate for the reduction in the salary limit to Executive Level II in the FY 2012 spending bill, and now have less funding for critical activities such as bridge grants to retain talented scientists or start-up packages for early-career and talented researchers.

We oppose the language in the bill that prohibits the NIH from using funds "for any economic research programs, projects or activities." Barring the funding of all research proposals that merely include the term "economics" in either the title or project description would impact nearly 4,000 active NIH awards. Many of these projects have important public health implications. For example, this provision could prohibit researchers from considering how socioeconomic factors contribute to health and disease, factors that are highly relevant with regard to diabetes, childhood obesity, cardiovascular disease, and rates of HIV infection.

Similarly, we urge the committee to reconsider the bill's language that prohibits funding "to support any patient-centered outcomes research," a provision that will thwart ongoing efforts to improve the quality and effectiveness of patient care, particularly when coupled with the committee's unwarranted elimination of the Agency for Healthcare Research and Quality.

And although we support the evaluation of the Clinical and Translational Science Awards program, the bill's prohibition on any program changes prior to the issuance of the Institute of Medicine review could deny NIH the ability to make rational management decisions in the interim.

We also wish to call attention to a provision that is not limited to NIH. Section 223 of the bill would prohibit the use of funds "for any program, project, or activity (PPA) related to research until" the Secretary of Health and Human Services (HHS) has certified that the PPA "is of significantly high scientific value" and has a "measurable" impact on public health. Section 223 also requires that the certification include "an explanation of how the success of the [PPA] will be measured with respect to its impact on public health." It is impossible to certify the impact of a research project before it has been conducted. Such a requirement will effectively eliminate the creative explorations that may lead to paradigm shifting basic discoveries and potentially innovative therapeutic approaches. Moreover, in the case of basic research projects, the public health impacts of major discoveries may not be realized for many years. Imposing these restrictions on fundamental research would delay important advances, at best, and, most likely, serve as a permanent barrier to advancing the most innovative and promising research.

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Requiring HHS to certify all NIH PPAs, Section 223 would also impose a crushing and wholly unnecessary administrative burden upon both the department and the agency. The NIH peer review process already requires reviewers to consider whether a proposed project addresses an important problem or critical barrier to the field and whether scientific knowledge, technical capability, and/or clinical practice would be improved if the project aims are achieved. Section 223 certification would be both redundant and far inferior to NIH peer review, which is conducted by thousands of independent volunteers from across the nation who have the relevant expertise to evaluate the scientific merit and potential public health impact of NIH grant applications. Implementing Section 223 certification also would divert the agency's limited resources from the core aspects of its mission.

NIH plays an enormous role in our nation's health and economic security. Additionally, the agency provides the cornerstone of our biodefense and is the foundation of our global dominance in biomedical innovation. The current bill, however, provides insufficient funds for NIH, imposes burdensome and duplicative certification requirements on NIH and HHS, and undermines the efforts of NIH to manage its portfolio effectively. Crippling NIH by freezing its funding while at the same time reducing its flexibility with well-intended but ill-conceived mandates will ultimately delay the search for cures and treatments intended to benefit the American people.

As the bill moves forward, we urge the Committee to reconsider the implications of this language and remove it from the final funding package, whether the bill moves independently or is made part of a larger spending measure.

We look forward to working with Congress, NIH, and the research community to sustain the nation's investment in medical research and ensure that NIH-funded research continues to seed the medical breakthroughs of the future.

Sincerely,

AcademyHealth

Academic Pediatric Association

Academy of Radiology Research

Albert Einstein College of Medicine of Yeshiva University

Alpha-1 Association

Alpha-1 Foundation

American Academy of Allergy, Asthma and Immunology

American Academy of Child and Adolescent Psychiatry

American Academy of Pediatrics

American Association for Dental Research

American Association for the Study of Liver Diseases

American Association of Colleges of Nursing

American Association of Colleges of Pharmacy

American Association of Oral and Maxillofacial Surgeons

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American Brain Coalition
American Chemical Society
American Congress of Obstetricians and Gynecologists
American Epilepsy Society
American Gastroenterological Association
American Heart Association
American Lung Association
American Pediatric Society
American Physiological Society
American Psychiatric Association
American Psychological Association
American Society for Bone and Mineral Research
The American Society for Cell Biology
American Society for Gastrointestinal Endoscopy
American Society for Microbiology
American Society for Pharmacology & Experimental Therapeutics
American Society for Reproductive Medicine
American Society of Biochemistry and Molecular Biology
American Society of Clinical Oncology
American Society of Human Genetics
American Society of Nephrology
American Society of Pediatric Nephrology
American Society of Tropical Medicine and Hygiene
American Sociological Association
American Speech-Language-Hearing Association
American Statistical Association
The American Thoracic Society
American Tinnitus Association
amfAR, the Foundation for AIDS Research
Associated Medical Schools of New York (AMSNY)
Association for Behavior Analysis International
Association for Clinical Research Training
Association for Patient-Oriented Research
Association for Psychological Science
Association for Research in Otolaryngology
Association for Research in Vision and Ophthalmology
Association of Academic Health Centers
Association of Academic Health Sciences Libraries (AAHSL)
Association of American Cancer Institutes
Association of American Medical Colleges (AAMC)
Association of American Universities
Association of Independent Research Institutes
Association of Medical School Pediatric Department Chairs
Association of Minority Health Professions Schools
Association of Public and Land-grant Universities

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Association of University Centers on Disabilities (AUCD)
AVAC: Global Advocacy for HIV Prevention
Barbara Ann Karmanos Cancer Institute
Benign Essential Blepharospasm Research Foundation
Biophysical Society
Brigham and Women's Hospital
Brown University
California Healthcare Institute
Cedars-Sinai Health System
Charles Drew University of Medicine and Science
Chicago Medical School/Rosalind Franklin University of Medicine and Science
Children's Environmental Health Network
The Children's Hospital of Philadelphia Research Institute
Christopher & Dana Reeve Foundation
Clinical Research Forum
Coalition for Health Funding
Coalition for the Advancement of Health Through Behavioral and Social Sciences Research (CAHT-BSSR)
Coalition for the Life Sciences
Coalition of Heritable Disorders of Connective Tissue
Coalition to Promote Research (CPR)
Cognitive Science Society
Collaborative for Enhancing Diversity in Science (CEDS)
Columbia University Medical Center
Commonwealth Medical College
Conference of Boston Teaching Hospitals
Consortium of Social Science Associations (COSSA)
Cooley's Anemia Foundation
COPD Foundation
Cornell University
Council on Governmental Relations
Creighton University
Crohn's and Colitis Foundation of America
Dana-Farber Cancer Institute
Digestive Disease National Coalition
Duke University School of Medicine
Dystonia Medical Research Foundation
Emory University School of Medicine
FasterCures
Federation of Associations in Behavioral & Brain Sciences
Friends of AHRQ
Genetic Alliance
George Washington University School of Medicine and Health Sciences
The Gerontological Society of America
Harvard Medical School

Heart Rhythm Society
Hepatitis B Foundation
HIV Medicine Association
Human Factors and Ergonomics Society
Huntsman Cancer Institute at the University of Utah
Huntington's Disease Society of America
Indiana University
Infectious Diseases Society of America (IDSA)
International Bipolar Foundation
International Foundation for Functional Gastrointestinal Disorders
Interstitial Cystitis Association
Intracranial Hypertension Research Foundation (IHRF)
The Johns Hopkins University
Joint Advocacy Coalition of ACRT, APOR, CRF, and SCTS
Karmanos Cancer Institute
Lehigh Valley Health Network
Lupus Foundation of America
Lupus Research Institute
March of Dimes
Massachusetts General Hospital
McLean Hospital
MdDS Balance Disorder Foundation
Medical Library Association (MLA)
Meharry Medical College
Mesothelioma Applied Research Foundation
The MetroHealth System
Michigan State University
Moffitt Cancer Center
Morehouse School of Medicine
The Mount Sinai Medical Center
National Academy of Neuropsychology
National Alliance for Eye and Vision Research
National Alopecia Areata Foundation
National Association of Pediatric Nurse Practitioners
National Association of State Head Injury Administrators
National Kidney Foundation
National Marfan Foundation
The National MS Society
National Organization for Rare Disorders
National Primate Research Centers
National Psoriasis Foundation
National Spasmodic Dysphonia Association
National Spasmodic Torticollis Association
National Women's Health Network
NephCure Foundation

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The New York Stem Cell Foundation
Northeastern University
Northwestern University Feinberg School of Medicine
NYU Langone Medical Center
The Ohio State University Wexner Medical Center
Parkinson's Action Network
Partners Healthcare
Penn Medicine
Penn State College of Medicine
Ponce School of Medicine and Health Sciences
Population Association of America and the Association of Population Centers
Psychonomic Society Governing Board
Pulmonary Hypertension Association
PXE International
Research!America
Roswell Park Cancer Institute
Saint Francis Hospital and Medical Center
Scleroderma Foundation
Sjogren's Syndrome Foundation
Sleep Research Society
The Social and Affective Neuroscience Society (SAN)
Society for Behavioral Neuroendocrinology
Society for Clinical and Translational Science
The Society for Computers in Psychology (SCiP)
Society for Industrial and Organizational Psychology (SIOP)
Society for Maternal-Fetal Medicine
Society for Pediatric Research
Society for Psychophysiological Research
The Society for the Psychological Study of Social Issues
Society for Women's Health Research (SWHR)
Society of Behavioral Medicine
Society of Mathematical Psychology
Society of Personality and Social Psychology
Society of Toxicology
Southern Illinois University
Spaulding Rehabilitation Hospital
Treatment Action Group (TAG)
Tulane University School of Medicine
Tuskegee University College of Veterinary Medicine, Nursing, and Allied Health
Unite 2 Fight Paralysis
University of California, San Francisco (UCSF)
University of Colorado Anschutz Medical Center
The University of Connecticut Health Center
University of Illinois
University of Kentucky

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University of Maryland School of Medicine

University of Massachusetts Medical School

University of North Carolina at Chapel Hill

The University of Texas System

University of Washington

University of Wisconsin School of Medicine and Public Health

US Hereditary Angioedema Association

Van Andel Institute

Vanderbilt University

Wake Forest School of Medicine

Washington University in St. Louis

Wayne State University School of Medicine

The Wistar Institute

Yale University