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
committee’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.
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
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
International 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
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