

The undersigned national organizations and institutions, which represent patients, scientists, and health care providers, wish to express their concerns about provisions for the National Institutes of Health (NIH) included in the fiscal year (FY) 2013 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 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 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 new young 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.

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, at best, delay important advances 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 is both unnecessary 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.