advancing the life sciences 1912-2012

FASEB
Federation of American Societies for Experimental Biology

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9650 Rockville Pike
Bethesda, MD 20814

*Now representing over 100,000 researchers and scientists*

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Society for Glycobiology (SFG)

September 5, 2012

The Honorable Hal Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Norm Dicks
Ranking Member
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Rogers and Ranking Member Dicks:

The Federation of American Societies for Experimental Biology (FASEB) represents 26 member societies and more than 100,000 scientists and engineers actively engaged in biomedical research supported by the National Institutes of Health (NIH) and other federal agencies. As such, we are deeply concerned about 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 18th, 2012. In addition to failing to reach 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 several policy provisions that, if implemented, would have a deleterious effect on the nation's biomedical research enterprise. Simply put, the House bill underfunds and over-regulates NIH.

FASEB recommends an NIH appropriation of at least $32 billion to sustain the research that capitalizes on the increasing scientific opportunities and the demonstrated capacity of the research enterprise. At $30.6 billion, the proposed funding level is substantially below the level necessary to maintain the current research effort. Without adequate funding, NIH will have to sacrifice valuable lines of research. The termination of ongoing studies and the diminished availability of grant funding will result in the closure of laboratories and the loss of high skill jobs. This failure to continue the federal investment in NIH will endanger the U.S.'s position as a world leader in biomedical research and also send a discouraging message to the talented young scientists we need to keep up with global competition.

The restrictive policy provisions included in the LHHS bill will jeopardize NIH's ability to do its job. The most damaging of those provisions, found in 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. It 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. In an August 3, 2012 *Science* magazine editorial, NIH Director Francis S. Collins, MD, PhD cited examples of NIH-funded basic research that led to major advances in the life sciences and pointed out that "today's basic research is the engine that powers tomorrow's therapeutic discoveries." 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.

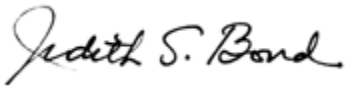
Requiring HHS to certify all NIH PPAs, Section 223 would also impose a crushing and wholly unnecessary administrative burden upon both the department and the agency. If applied to FY 2011 for example, this provision would have required the certification of each of the 63,755 grants, contracts, and awards funded by NIH. 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 would also divert the agency's limited resources from the core aspects of its mission.

Another policy provision that is particularly troubling is the prohibition on the use of funds for "any economic research" PPA. Barring the funding of all research proposals that merely include the term "economics" in either the title or project description would impact 3,965 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; we already know that these factors are highly relevant with regard to diabetes, childhood obesity, cardiovascular disease, and rates of HIV infection.

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. For example, 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. Further lowering the maximum rate of salary that can be charged to grants and other extramural mechanisms from Executive Level II to Executive Level III may have a deleterious effect on the research enterprise. As the second rate reduction in two years, this could destabilize existing research teams, end promising projects, and force talented investigators out of science altogether. 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.

FASEB appreciates your commitment to improving the nation's health. 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. We look forward to working with Congress, NIH, and the research community to sustain the nation's investment in biomedical research and ensure that NIH-funded research continues to seed the medical breakthroughs of the future. Please let us know if FASEB can provide additional information or be of further assistance.

Sincerely,



Judith S. Bond, PhD
FASEB President

CC: All members of U.S. House of Representatives Committee on Appropriations

All members of the U.S. Senate Committee on Appropriations