March 4, 2015

The Honorable Fred Upton
U.S. House of Representatives
Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
Energy & Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member DeGette:

The Federation of American Societies for Experimental Biology (FASEB) comprises 27 scientific societies, collectively representing over 120,000 biological and biomedical researchers. We thank the Energy and Commerce Committee for focusing its attention on the discovery process and your efforts to ensure that we can take full advantage of the advances the country has made in science and technology. The opportunities for progress have never been greater, yet major obstacles, including funding constraints imposed by the Budget Control Act, are preventing us from achieving all of the possibilities available today.

In January, FASEB released an analysis of the threats to continued progress in biological and medical science research. Sustaining Discovery in Biological and Medical Science: A Framework for Discussion examined the challenges facing researchers and presented a series of recommendations to alleviate them. The FASEB report documented how shortfalls in federal funding and rising regulatory costs have constrained research budgets. At the same time, scientific opportunities have expanded, the research workforce has grown, and thus, more individuals are seeking support for research projects. These opposing trends have resulted in an increasingly unstable research enterprise, delaying scientific discovery.

FASEB appreciates the opportunity to comment on the discussion draft of the 21st Century Cures legislation. We are, however, disappointed in the sections of the 21st Century Cures proposal that are focused on the National Institutes of Health (NIH). The discussion draft lacks a comprehensive statement about the fundamental problems affecting the United States research enterprise as articulated by recent reports and papers including the FASEB Sustaining Discovery report, “Restoring the Foundation: The Vital Role of Research in Preserving the American Dream” (Norm Augustine and Neil Lane, American Academy of Arts and Sciences), and “Rescuing U.S. Biomedical Research From Its Systemic Flaws” (Bruce Alberts, Marc Kirschner, Shirley Tilghman, and Harold Varmus). In addition, the NIH provisions fail to provide a coherent set of recommendations, do not address the major issues slowing research progress, and do not incorporate important corrections to current procedures.

Our concerns cover the following four basic themes: redundancy with existing regulations; omission of key sections; micromanagement of agencies that could hinder future progress; and contradictory and superfluous provisions.
There is extensive redundancy with existing laws, rules, and policies

Overlapping and redundant regulations increase the cost of research and decrease the amount of time scientists spend conducting actual research. Indeed, the Federal Demonstration Partnership found that faculty in the biological, health, and agricultural sciences spend more than 40 percent of their grant-funded time on administrative tasks.\(^1\) Patchwork regulations also make it challenging for institutions and investigators to ensure full compliance. Several items within the proposed bill duplicate existing regulations and practices.

Section 2081 amends the Public Health Service Act to establish a publicly-accessible database for clinical trial registration and results. However, Section 801 of the Food and Drug Administration Amendments Act (FDAAA) mandated the creation of such a database in 2007 (www.ClinicalTrials.gov).

Greater data sharing for NIH-supported projects is proposed, in Section 2201 of the draft bill. A 2013 memorandum issued by the Office of Science and Technology Policy (OSTP) (“Increasing Access to the Results of Federally Funded Scientific Research”) already requires research agencies, including NIH, to develop plans to increase public access to research data. This memorandum also provides a comprehensive list of circumstances of when mandatory data sharing is not required.

A database for re-evaluation and re-use of clinical research data could enhance scientific rigor and minimize duplicative research efforts. However, the database described in Section 2082 would have limited value due to the small number of data categories that can be shared without risking participant privacy. Technological and scientific advances continue to expand the types and combinations of data that can be used for re-identification. Alternative methods to make data available for analysis while still protecting privacy are being developed by NIH and the Agency for Healthcare Research and Quality; to maximize benefit, databases require the flexibility to take full advantage of improved methods and practices.

There are several programmatic redundancies established within the draft bill that may increase inefficiency and lead to additional overlapping and duplicative regulations. For example, the Innovative Cures Consortium’s mission, as established in Section 2001, is remarkably similar to that of the National Center for Advancing Translational Sciences. Also, Section 4002 establishes a working group to address administrative burden in biomedical research. Several federal advisory groups, including the National Science Board and the National Academies of Sciences, are already addressing this issue. Therefore, a new working group is not warranted. This working group is also directed to provide recommendations on restructuring, streamlining, and simplifying grant proposal submission at NIH. Currently, however, NIH has three separate groups examining this very issue (the Scientific Management Review Board, the Center for Scientific Review, and the Advisory Committee to the Director).

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Several important sections are missing from the bill text

Several sections of the 21st Century Cures draft legislation, including those that address work-related travel of federal researchers, regulation of diagnostics, and proposed authorization levels, have been left blank. These sections could significantly impact the research enterprise. Therefore, it is critical that the text be provided to stakeholders as soon as possible so that the implications of the proposed legislation can be evaluated in toto.

Travel restrictions placed upon federal researchers continue to be an area of major concern. Recent policy changes have disrupted the research programs within several agencies. Federal scientists face more barriers to attend professional meetings which are essential for sharing research findings and identifying new opportunities for collaboration. Some federal clinical researchers have encountered difficulties attending continuing education courses necessary to maintain licensure. Unfortunately, the text addressing travel of NIH and Food and Drug Administration (FDA) employees is omitted from sections 4003 and 4101 and, as a result, the bill does nothing to correct the problems caused by the restrictions on travel.

The title of Section 2161 suggests that it may include regulation of Laboratory Developed Tests (LDTs). Based on the responses to the FDA’s proposed regulatory framework for LDTs, it is evident that establishing regulation that both ensures quality of the tests and promotes innovation will be challenging. Again, the bill text for this section was omitted.

FASEB has described the benefits of multi-year budget authority for research agencies, including NIH, in its Sustaining Discovery report. Under the current yearly funding authority, the frequent delays in passage of appropriations bills compress the time available for funding decisions by NIH. In a typical year, NIH is forced to return $300 million to the Treasury (one percent of its budget) because of the yearly spending limits. The ability to carry over funding into the next fiscal year would permit more efficient management of grant dollars. We understand that this mechanism was recommended to the Committee and are disappointed to see that it was not included in this draft.

The major constraint on research progress is inadequate funding, yet the bill does not address this critical problem. Sustained and predictable funding is critical to maintain a highly productive research enterprise. However, since FY 2003, NIH has lost more than 23 percent of its capacity to support research due to a combination of budget cuts and inflationary losses. These losses have reduced the number of grants available and prematurely terminated many promising research projects and careers. While the goals of this draft bill are well intentioned, sufficient fiscal support is indispensable to fully realize them.

Many provisions legislate activities already underway, would micromanage NIH, and could interfere with decision making based on scientific merit

The draft bill is overly prescriptive regarding how its goals should be accomplished. While some of the bill’s provisions may lead to short-term benefits, the highly specific bill language will limit severely the
ability of federal agencies to adapt to future research challenges. Similarly, oversimplification of some issues within the bill will increase the likelihood of inadequate and inefficient solutions.

Careful planning and management of the NIH budget is important. However, Section 4001 of the draft bill mandates the creation of an NIH-wide strategic investment plan that defines extremely narrow parameters to determine funding priorities. Legislatively establishing a set of priorities will hinder progress by constraining inquiry. It will politicize the search for cures and create a never-ending competition for targeted funding, limiting the discretion and judgment of the scientific leadership at NIH. This provision is duplicative with existing practices as all NIH institutes and centers (I/Cs) already develop strategic plans. Furthermore, it is unlikely that establishing 10 trans-NIH “strategic focus areas” as proposed in the bill, would enhance research planning within individual I/Cs. Currently each I/C establishes its strategic plan based on its specific mission and scientific opportunity, and this is superior to using a general list of “focus areas.”

Declining research funding, the limited number of faculty positions, and the increasing length of training all contribute to the instability of the biomedical workforce and the rising median age at which investigators receive their first major research grant. In sections 2261 and 2262, however, these issues are reduced to problems associated with how grants are awarded. The proposed adjustments will not address systematic workforce challenges and will likely shift some of the pressure to other career stages. NIH has already established provisions to help early career scientists, and their grant success rates are similar to those of experienced scientists. Also, NIH has issued analyses of the workforce and early career scientists, rendering the additional report mandated in the bill redundant.

**Some sections are contradictory or superfluous in scope**

Some sections within the draft bill appear to have been added in isolation, with no knowledge or regard for subsequent provisions. For example, Section 4005 requires the Comptroller General to submit to Congress an analysis of the use and impact of Common Fund monies. One page later, Section 4007 authorizes additional funding for the Common Fund, effective before the Comptroller General’s report is released. Other provisions address matters that are not critical issues. To increase accountability, the bill institutes four year term limits for NIH I/C Directors in Section 4004. Considering that I/C Directors can already be removed from their positions, and that the strategic plans they develop (Section 4001)—on which their performance is judged—are longer than the proposed terms, the utility of this provision is questionable. Similarly, legislating the type of statistics (e.g. Bayesian methods) the FDA must accept for the review and approval of new drugs and medical devices is not likely to impact the rate at which new cures reach the public. It is also redundant with existing FDA guidance issued in 2010 on the use of these statistical methods.

This is a large, complex bill covering many agencies and issues. Our comments focus on the area we know best, NIH funded research. We appreciate, however, that some provisions of the bill are helpful to physicians and their patients. Title, IV Subtitle S, Continuing Medical Education Sunshine
Exemption, for example, makes an important correction to the Sunshine Act by excluding peer-reviewed journals, journal reprints, journal supplements, and medical textbooks from the reporting requirement. This removes a barrier that limited physicians’ access to a valuable source of scientific information.

FASEB appreciates the Energy and Commerce Committee’s concern for the future of biomedical research, and we share your desire to ensure that the U.S. remains a world leader in biomedical research. We encourage the committee to streamline future versions of the legislation and to focus the next draft on the major impediments to research progress. Within the next few weeks, FASEB will submit additional comments offering specific language to improve the draft bill.

Sincerely,

Joseph R. Haywood, PhD
FASEB President