



April 9, 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) thanks the Energy and Commerce Committee for its efforts to engage stakeholders in crafting the 21<sup>st</sup> Century Cures legislation. FASEB is comprised of 27 scientific societies which collectively represent over 120,000 biological and biomedical researchers. We previously submitted [comments](#) on the initial draft; the recommendations provided herein would significantly improve the proposed bill as well as address concerns that have been raised by our colleagues in the biomedical research community. Our suggestions focus on provisions concerning the National Institutes of Health (NIH) and address three basic themes: redundancy with existing regulations; micromanagement that could hinder future progress; and omission of key sections.

### **There is extensive redundancy with existing laws, policies, and agency activities**

FASEB identified a number of provisions that duplicate existing regulations and practices; other sections propose creating new research and advisory entities whose missions, operations and functions parallel those of existing programs. Overlapping regulations increase the cost of—and decrease the time spent—conducting research. Similarly, funding multiple enterprises with comparable goals increases the burden on taxpayers and could lead to redundancy in effort. **The following sections of the bill are duplicative with existing regulations or ongoing efforts and should be deleted.**

<b>Section and Title</b>	<b>Effort or Regulation Duplicated</b>
Section 2001. Innovative Cures Consortium	<p>A number of institutions are currently engaged in work that mirrors the mission and operations of the proposed Consortium. They are:</p> <ul style="list-style-type: none"> <li>• The <a href="#">National Center for Advancing Translational Sciences</a> (NCATS) was created specifically to speed the delivery of cures to patients. NCATS partners with small businesses through its Small Business Innovation Research and Small Business Technology Transfer programs. NCATS' Clinical and Translational Science Awards program promotes collaboration among medical research institutions, and the Cures Acceleration Network provides NCATS with flexible funding mechanisms</li> </ul>

	<ul style="list-style-type: none"> <li>• The <a href="#">Critical Path Institute</a> is a public-private partnership (PPP) focused on developing drugs for numerous high-profile diseases</li> <li>• The <a href="#">Accelerating Medicines Partnership</a> is a PPP working to identify and qualify biomarkers to increase the availability of diagnostics and therapies for patients</li> </ul>
Section 2021. Medical Product Innovation Advisory Committee	<p>The review of medical product innovation described in Sec. 2021 has already been done:</p> <ul style="list-style-type: none"> <li>• The 2011 Institute of Medicine report “<a href="#">Medical Devices and the Public Health</a>” provided an extensive review of FDA review and approval processes, as well as recommendations for facilitating innovation in the medical device industry</li> <li>• The 2014 RAND Corporation report “<a href="#">Healing Medical Product Innovation</a>” presents ten areas of focus for increasing medical product development and innovation</li> </ul> <p>Furthermore, the <a href="#">Medical Device Innovation Consortium</a> is a nonprofit PPP created in 2012 with the goal of improving patient access to cutting edge medical technologies by better managing regulations impacting the medical device industry—nearly the same goal as the proposed Advisory Committee.</p>
Section 2081. Standardization of data in clinical trial registry data bank on eligibility for clinical trials	<p>Section 801 of Food and Drug Administration Amendments Act of 2007 expanded the National Library of Medicine’s clinical trials registry and results database, <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a>. The data fields described in Sec. 2081 were incorporated into <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a> through that mandate. Additionally, recent proposed guidelines from HHS and NIH, if enacted, would further expand the types of data reported and the types of trials required to register with the database.</p>
Section 2082. Clinical trial data system	<p>NIH and Agency for Healthcare Research and Quality are supporting research and development of systems that would allow approved groups to perform statistical analyses on a database without having access to the raw data (e.g. <a href="http://srdr.ahrq.gov/">http://srdr.ahrq.gov/</a> and <a href="https://www.phenxtoolkit.org/index.php">https://www.phenxtoolkit.org/index.php</a>).</p>
Section 2201. Sharing of data generated through NIH-funded research	<p>As a result of the 2013 Office of Science and Technology Policy (OSTP) memorandum “<a href="#">Increasing Access to the Results of Federally Funded Scientific Research</a>,” agencies, including NIH, have already started developing procedures and techniques to</p>

	facilitate greater access to data.
Section 2262. Report on the trends in age of recipients of NIH-funded major research grants	The 2012 Biomedical Research Workforce Working Group <a href="#">Report</a> presented detailed analyses of this issue. Implementation activities of recommendations presented in the report are ongoing. Current information on new investigators is provided in the <a href="#">NIH Data Book</a> .
Section 4002. Biomedical research working group to reduce administrative burden on researchers	<p>Several studies have already documented this problem:</p> <ul style="list-style-type: none"> <li>• Federal Demonstration Partnership Faculty Surveys (<a href="#">2007, 2012</a>)</li> <li>• 2014 National Science Board report <a href="#">“Reducing Investigators Administrative Workload for Federally Funded Research”</a></li> </ul> <p>The 2014 National Academy of Sciences Committee on Federal Research Regulations and Reporting Requirements is currently examining the issue, as are several federal agencies (USDA, NSF) and multiple NIH groups (Advisory Committee to the Director, Center for Scientific Review, and Scientific Management Review Board).</p> <p>In addition, Rep. Comstock (R-VA) sponsored legislation (H.R. 1119) to establish an OSTP working group to recommend how to streamline regulations and reduce reporting burden for all federally-funded investigators, including NIH.</p>

**Many provisions would micromanage NIH and could interfere with decision making based on scientific merit**

The draft bill is overly prescriptive—yet concurrently overly simplistic—regarding how its goals should be accomplished. While some provisions may lead to short-term benefits, they would ultimately limit NIH’s ability to adapt to future research challenges.

The plight of early career scientists has received national media attention, but as a group they fare nearly as well as more experienced investigators in terms of grant success rates. The underlying problem is that too few research project grants are being awarded as a result of decreases in funding and spending power for NIH. **Section 2261, which increases funding specifically for new investigators, should be eliminated.** Increased funding solely for early career researchers, without concomitant increases for all applicants, will only shift the burden to other career stages.

Similarly, the call to fund more high-risk, high-reward science by NIH institutes and centers (I/Cs) in Section 2281 without allocating new monies to do so means that other essential research will suffer. Moreover, the Common Fund already has four dedicated high-risk, high-reward programs that support research in areas of interest to all I/Cs. **Unless additional funds are provided, FASEB recommends deleting Section 2281.**

The NIH-wide, five-year strategic investment plan proposed in Section 4001 is unnecessary. The vast majority, over 94 percent, of the NIH budget is allocated to I/Cs, which already develop their own strategic plans. Research sponsored by I/Cs lays the foundation for advances that will affect hundreds of diseases and multiple demographic groups. With scientific knowledge and opportunities expanding rapidly, there is enormous potential for breakthrough discoveries with wide-ranging benefits. However, the narrow parameters set for determining funding priorities in the draft legislation will politicize the funding process and hinder scientific progress by constraining inquiry. **Section 4001 is misguided and should be removed.**

Despite the section's title, provisions in Section 4004 directed at NIH I/C directors will do little to improve accountability. Subsection (a) would establish four-year term limits. With the exception of the National Cancer Institute, all I/C heads are appointed by and serve at the pleasure of the NIH director. Setting arbitrary term limits for directors will not improve I/Cs' productivity, but will likely impede future recruitment for these positions. Subsection (b) requires I/C directors to personally review and ensure that all new R-series grants are in the public interest and worth the investment. I/C directors already give final authorization for grants after they have undergone multiple rounds of review by experts in the field who scrutinize their scientific merit, innovation, and feasibility. However, while the social and economic value of a broad portfolio of research can be demonstrated, the benefits that will arise from any given research project cannot always be assessed in advance. This concept is a fundamental aspect of basic research, and it cannot be overstated that pursuing knowledge for the sake of knowledge, without expectation of benefit or reward, is the driving force behind some of the most important advances in health and medicine. These provisions suggest an underlying mistrust of the peer review process that is viewed as the gold standard for evaluating research and which other nations have strived to copy; therefore, **FASEB recommends removing subsections (a) and (b) from Section 4004.**

### **Several important sections are missing from the bill text**

Finally, the discussion draft left blank several sections which could significantly impact the progress and success of the research enterprise. To ensure that the intent of the bill is achieved, FASEB would like to see the committee incorporate the following suggestions into the next draft.

It is our understanding that Section 2161, under Title II, Subtitle J – Modernizing Regulation of Diagnostics, will address regulation of laboratory developed tests (LDTs). The oversight of LDTs is a complex topic that affects many different endeavors. Discussions on the proper mechanism for regulating

LDTs have been divisive across the healthcare and research communities and have spanned decades. **The committee should consult the [comments](#) submitted to FDA on this guidance to gauge the sentiments of the healthcare ecosystem in which LDTs are developed and administered before finalizing any language on their regulation.**

Travel restrictions imposed on federal workers as a result of Executive Order 13589 and subsequent Office of Management and Budget memorandum M-12-12 have had unintended but dramatic consequences for researchers and clinicians at federal agencies. The limits on conference budgets and attendance at scientific meetings have led to a substantial decrease in participation by federal researchers, some of whom are missing out on continuing medical education credits they need to maintain licensure. **FASEB recommends that federal researchers and clinicians be exempt from these restrictions, and that language be added to Sections 4003 and 4101, on NIH and FDA travel, respectively, to reflect this.** Such language was included, for example, in the original text of the Senate Labor-HHS Appropriations Bill for fiscal year 2015:

“SEC. 526. (a) None of the funds in this Act may be available for agencies, or in the case of an agency with multiple bureaus, each bureau (or operating division) to support: (1) More than 50 agency employees on official travel away from their duty station to attend a particular conference; or (2) More than \$1,000,000 for sponsoring a conference. (b) This section shall not apply to conferences that are scientific in nature or scope.”

Sustained and predictable funding is essential to maintain a highly productive research enterprise, but the bill does not address this critical problem. Furthermore, a long-term plan for increasing federal investment in research and development is necessary to restore the constant dollar losses in funding that have reduced the NIH budget by over 20 percent since 2003. **FASEB recommends granting multi-year budget authority to NIH through the 21<sup>st</sup> Century Cures Act, along with a commitment to increases in appropriations of at least five percent annually for the next five years.** This would enable thoughtful planning and efficient use of funding, and parallels suggestions from the American Academy of Arts and Sciences in its 2014 report “Restoring the Foundation: The Vital Role of Research in Preserving the American Dream.” Sample text should read:

SEC. 4010. AUTHORIZATION OF APPROPRIATIONS.

(a) Funding.— 402a(1) of the Public Health Service Act (42 U.S.C. 282a(1)) is amended to read as follows:

``SEC. 402A. AUTHORIZATION OF APPROPRIATIONS.

``(a) In General.--For the purpose of carrying out this title, there are authorized to be appropriated--

``(1) \$32,000,000,000 for fiscal year 2016, to remain available until September 30, 2017; and

``(2) such sums as may be necessary for fiscal year 2017, to remain available until September 30, 2018.

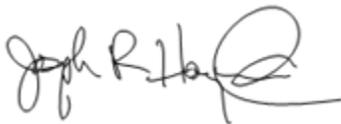
``(3) such sums as may be necessary for fiscal year 2018, to remain available until September 30, 2019.

``(4) such sums as may be necessary for fiscal year 2019, to remain available until September 30, 2020.

``(5) such sums as may be necessary for fiscal year 2020, to remain available until September 30, 2021.

FASEB appreciates the Energy and Commerce Committee's concern for the future of biomedical research. The opportunities for progress have never been greater, but we must move forward in a way that stimulates and encourages innovation. We encourage the committee to thoughtfully consider how best to incorporate these suggestions into the next draft of the 21<sup>st</sup> Century Cures Act.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph R. Haywood". The signature is fluid and cursive, with a large, stylized initial "J" and "H".

Joseph R. Haywood, PhD  
FASEB President