ENDOCRINE SOCIETY
Hormone Science to Health

June 2, 2014

2183 Rayburn House Office Bldg
United States House of Representatives
Washington, D.C., 20515

Dear Chairman Upton and Representative DeGette,

The Endocrine Society appreciates the opportunity to respond to the questions posed by the "21st Century Cures: A Call to Action" whitepaper. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. Our membership includes over 17,000 researchers and clinicians working to discover, develop, and deliver new cures and therapies to patients worldwide. We are therefore encouraged by the new 21st Century Cures Initiative and support your efforts to optimize the biomedical research cycle.

The Endocrine Society would like to emphasize that administrative tasks in the conduct of research represent an increasing burden on investigators. Furthermore, excessive administrative workload wastes critical taxpayer dollars and delays the conduct and completion of life-saving research by increasing the amount of time investigators must spend writing grants. Uniform templates for grant applications and reports, which require minimal formatting, would save time without reducing information content. Automated data transfer between PubMed Central and eCommons—including the RPPR grant reporting system—would eliminate unnecessary duplication of effort.

Additional potential solutions include, for example, expanded utilization of Central Institutional Review Boards (CIRBs) for multi-site studies. This strategy has the potential to minimize administrative burdens associated with clinical trials. The Endocrine Society therefore recommends that the Committee encourage the Office for Human Research Protections to issue guidance on the implications of using CIRBs and provide assurance that users of CIRBs are protected from additional liability.[1] Also, the Committee should encourage federal agencies to standardize forms between different federal research agencies and across funding mechanisms as described in the recent National Science Board report[2].

Another critical issue that strongly affect the translation of biomedical research to therapeutic inventions is the rigor with which biomedical research is undertaken. Unless the basic research that informs drug development is sufficiently holistic, rigorous and thus replicable, downstream R&D could be based on fundamentally flawed information, thus wasting resources and potentially injuring clinical research volunteers. The NIH is proactively

[1] Endocrine Society Position Statement on Central IRBs. Accessed May 20, 2014
[2] http://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf. Accessed May 27, 2014

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addressing this issue through a number of ongoing initiatives[3], and we encourage the Committee to support these efforts and work with the NIH to identify ways to enhance the quality of research outcomes and reporting of research methods. Specifically, we recommend that the Committee identify incentives for researchers and institutions that encourage independent validation of basic science studies with potential clinical application.

In addition to the reproducibility of basic research, the generalization of data requires that all stages of the biomedical research cycle include a consideration of sex differences in research subjects where appropriate. A significant component of the rigor and completeness in research is the investigation of sex specific effects. Despite decades of awareness of the issue, women are still inadequately represented in many clinical trials. Additionally, sex differences are still not routinely considered as a critical variable in basic biological studies. This critical inconsistency in the biomedical research pipeline can have serious consequences. For example, of the 10 drugs that were withdrawn from January 1, 1997 through 2001, 8 posed greater health risks for women[4].

The NIH and FDA are working to address this important issue; for example, the FDA is required to develop an Action Plan that includes an "analysis of the extent to which demographic subgroups, including sex, age, racial, and ethnic subgroups, are represented in clinical studies to support applications for approved or licensed new molecular entities, biological products, and devices[5]. Additionally, the NIH is developing new policies to ensure that preclinical research includes consideration of sex differences in cell and animal models[6]. The Endocrine Society therefore recommends that the Committee ensure that the NIH and FDA adopt policies that support the consideration of sex as a biological variable and that these policies are efficiently implemented and widely adopted without introducing excessive financial and administrative burdens on preclinical researchers.

We would like to further emphasize that education and mentorship are extremely important as the frontiers of biomedical knowledge progress towards more complicated and interdisciplinary techniques, analysis, and interpretation. It is, therefore, necessary that there are investments in the current generation of scientists, in the forms of steady funding mechanisms, to ensure our scientific future. Trainees and students should be engaged at all stages of education to promote a greater understanding of the biomedical research cycle and the role of federal research investments in the development of cures and treatments for diseases. Mentors and trainees should also be encouraged to explore opportunities to collaborate with partners in the private sector.

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[3] NIH Plans to Enhance Research Reproducibility. Accessed May 20, 2014

[4] http://www.gao.gov/new.items/d01286r.pdf Accessed May 20, 2014

[5] http://www.fda.gov/downloads/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdasia/ucm365544.pdf. Accessed May 20, 2014

[6] Policy: NIH to balance sex in cell and animal studies. Accessed May 20, 2014

Finally, while we appreciate the need to accelerate the process from basic discoveries through delivery of new therapies to the extent possible, research is by nature a labor- and time-intensive process that relies on validated discoveries and consistent replication to build an expanding foundation of knowledge for complicated biological systems. Reliable and protected sources of federal research funding will allow researchers to effectively and responsibly continue to make new discoveries and to explore innovative research areas, especially for diseases diseases such as obesity, diabetes, and osteoporosis. The increasing global burden of these chronic disease make regular investment in human health an urgent priority.

Thank you for considering the Endocrine Society's comments and for your strong and continuing support of biomedical research. We hope that our recommendations are helpful as you consider legislative solutions and regulatory barriers to the efficient progress of biomedical science. If we can be of any further assistance in your efforts, please do not hesitate to contact Joseph Laakso, Associate Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

Teresa K. Woodruff, PhD
President,
Endocrine Society