

February 1, 2019

Kelvin Droegemeier, PhD
Director, Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Dr. Droegemeier,

On behalf of the Endocrine Society, I would like to congratulate you on your appointment to lead the White House Office of Science and Technology Policy (OSTP).

The Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. Our member scientists and clinicians are at the core of solving many of the most pressing health problems of our time, from diabetes and obesity to infertility, bone health, thyroid conditions, and hormone-related cancers. These diseases affect growing numbers of people, placing stress on the health care system. Our more than 18,000 members include basic scientists who study fundamental hormone biology and pathways, clinical researchers who explore how those same pathways and systems are involved in human disease, and clinical practitioners who apply new scientific knowledge to deliver new therapies and improved care for patients. We promote policies that will increase the effectiveness of the biomedical research enterprise and ensure a sustainable pipeline of researchers so that the United States remains a world leader in science.

As you assume your role and begin to work on your focus areas of coordinating the federal research and development portfolio, helping to produce a diverse STEM workforce, and supporting new models of public-private partnership that can translate research into the market place, we would like to offer our assistance to you. We believe we share many goals and priorities, including the concern that unnecessary burden on researchers is a growing threat to science and technology in America.

Attached please find a summary of our policy priorities and positions that are relevant to the work of the OSTP. If we can be of assistance, please do not hesitate to contact our director of science policy Joseph Laakso at jlaakso@endocrine.org.

Sincerely,



Susan Mandel, MD
President, Endocrine Society



Federal funding for biomedical research:

Endocrine scientists funded by federal agencies continue to make remarkable contributions in areas of critical national interest, including diabetes, obesity, the microbiome, cancer, bone health, and fertility.

President Trump has emphasized the importance of the United States maintaining its place as the global leader in all sectors. Biomedical research is an area where the country is losing its place as the top generator of scientific discovery. The lack of sustained federal support compounded by austerity measures such as sequestration has created a “brain drain,” as gifted scientists pursue other careers or leave the US to develop important breakthroughs and therapies elsewhere, while young people opt out of biomedical research careers. Without steady, sustained increases in federal support for biomedical research and the National Institutes of Health (NIH), other countries will fund groundbreaking new cures and treatments and replace the United States as the global leader in biomedical research.

Future opportunities to cure many diseases will decrease as the government’s investment in biomedical research declines. For FY 2020, we support an increase of at least \$2.5 billion for NIH over the final FY 2019 budget to make up for years of flat funding and under-investment and to maintain America’s status as a leading biomedical research engine.

Regulatory burdens in research:

Clinical and basic scientists receiving federal support are often negatively affected by the time and effort required to comply with administrative requirements imposed by granting agencies and their home institutions. For example, grant forms are often not standardized across agencies, creating redundancies, and there can be multiple layers of administrative approval for forms, necessitating advanced due dates.

In addition to the burden on investigators, the excessive administrative burdens waste taxpayer dollars and delay the completion of lifesaving research. The high expense of these administrative and regulatory tasks also results in an increasingly unequal playing field for biomedical researchers at many institutions across the country. As the Administration examines opportunities to reduce federal regulations, we encourage you to consider opportunities to reduce onerous regulatory burdens faced by researchers.

Endocrine Disrupting Chemicals

The impact of endocrine-disrupting chemicals (EDCs) on public health is a top research, clinical, and policy issue for the Society. Current testing guidelines and regulatory approaches are insufficient for identifying EDCs that cause harm; factors that should be considered in assessments of chemicals for hormone interference include: windows of sensitivity during human development (e.g., fetal development, puberty); vulnerable populations such as pregnant women and children; low-dose effects and non-monotonicity; and appropriate endpoints that predict harms for EDCs. We strongly encourage OSTP to promote the use of systematic review frameworks in chemical evaluations. We also encourage OSTP to include endocrine experts in discussions related to the evaluation of scientific data for endocrine effects, and we would be happy to identify appropriate experts.



Publishing and Peer Review

As a publisher of high-quality scientific journals, the Endocrine Society recognizes the important role that peer-review and editorial processes play in the curation and dissemination of reliable and reproducible scientific information. While we support increased access to scientific information, including open access publications such as the *Journal of the Endocrine Society* (JES), we are concerned about the potential impact on scientific research and publication brought about by increased adoption of Plan S by research funders. Researchers funded by Plan S would be unable to publish in most high-quality journals, without control over republication, commercial use, and derivative works by third parties. Other details of Plan S remain vague or unexplained in terms of operational application. For example, it remains uncertain how journals and authors will be able to adapt to a business model reliant on the “capped” article processing charges (APCs) that Plan S funders have undertaken to announce. We urge OSTP to clarify the Administration’s position on Plan S and to recognize the value of hybrid journal publications as a route to achieving open access in a diverse publishing ecosystem.

Standardization of Hormone Assays

The correct diagnosis and effective treatment and prevention of many diseases depend on accurate measurement of hormones. Many blood tests for hormones exist and assuring that all tests are sufficiently accurate and reliable is necessary for health care providers to make treatment decisions based on sound data. The Society is a founding member of the Partnership for the Accurate Testing of Hormones (PATH), which works with the Centers for Disease Control and Prevention Hormone Standardization Program to standardize hormone tests and to engage stakeholders to promote high quality hormone tests. We support standardization of hormone assays conducted by the Centers of Disease Control and Prevention and expansion of its efforts to standardize testing and establish standardized reference ranges for more hormones.