



**February 11, 2016**

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## **Advocacy News**

### **President Unveils FY2017 Budget; Endocrine Society Disappointed in Decreases in Areas of NIH**

Congress and the administration this week are primarily focused on proposed details of fiscal 2017 spending. The White House unveiled its annual budget proposal on Tuesday, February 9. The budget proposal would give the National Institutes of Health (NIH) \$33.1 billion, a 2.6 percent raise over 2016. The money would include \$680 million for [Vice President Biden's cancer moonshot](#); \$100 million more for the Precision Medicine Initiative's 1-million person cohort study; and \$45 million in added funds for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative. However, the new money for these presidential priorities plus \$1 billion from NIH's existing budget would come out of so-called mandatory funds, which require Congress to establish a dedicated funding stream and are likely to be a hard sell in Congress.

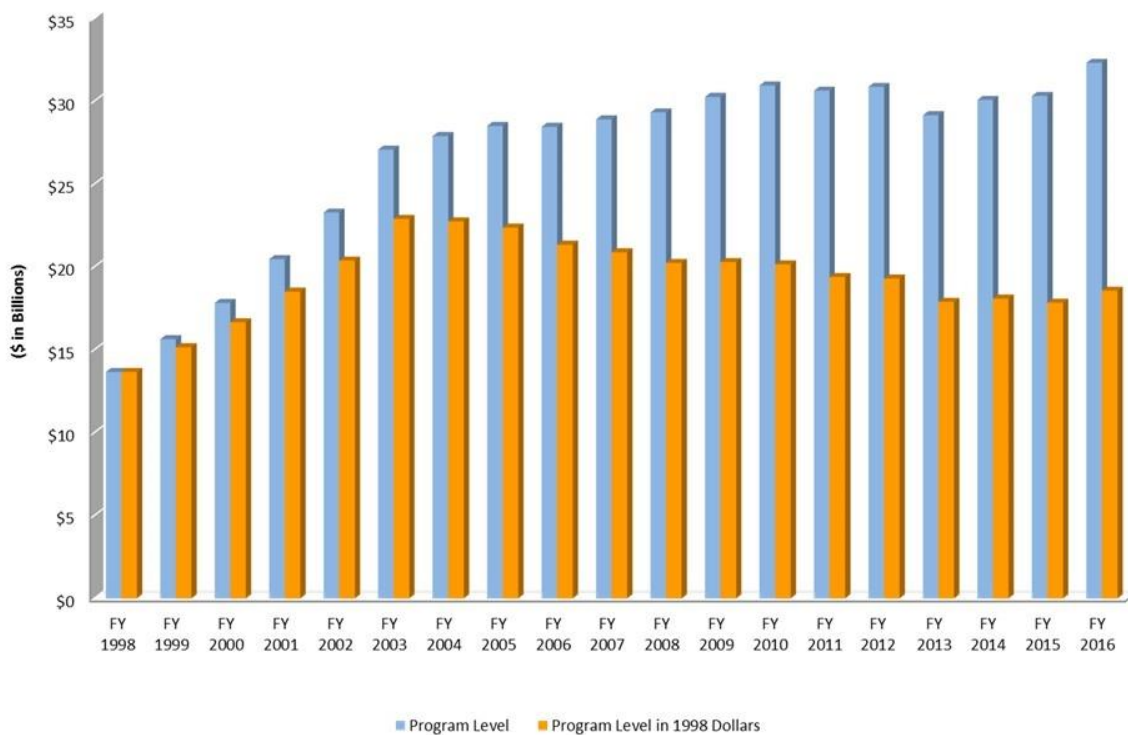
In addition, even if that money came through, aside from the three targeted programs, all of NIH's 27 institutes and centers except the National Cancer Institute would receive a 0 percent increase. The number of research grants funded would rise by 600 to 36,440, but new and competing would drop by 807 grants to 9,946. As a result, NIH expects the success rate, or the portion of reviewed grants that receive funding, to drop from 19.2 percent to 17.5 percent.

**Where We Stand:** The Endocrine Society is extremely concerned about the impact of the proposed budget on investigator-initiated research and worries about the ability to establish a mandatory funding stream. While we appreciate that President Obama's overall goal is to increase funding for biomedical research, we are disappointed his proposed budget would actually decrease the baseline funding level for the NIH in FY2017. Further, while we commend the president's inclusion of funding to support cancer-related research activities, we are disappointed that the

proposed budget reduces funding for research aimed at diabetes and a host of other endocrine-related diseases affecting our nation’s health. The Endocrine Society will continue to advocate for increased appropriations needed to put the NIH back on a sustainable growth path, make up for more than a decade of flat funding, and continue the important progress gained by last year’s \$2 billion increase for the NIH.

**Next Steps:** The President’s Budget is just a starting point for funding decisions. Attention now will shift to the House and Senate appropriations committees. The Endocrine Society will continue to advocate strongly for NIH funding. As appropriators begin to discuss this issue, we will launch an on-line advocacy campaign so Endocrine Society members can urge Congress to support biomedical research funding.

NIH Program Level in Nominal Dollars and Constant Dollars



**Additional Resources:**

- [OMB Budget Hub](#)
- [Fact Sheet - Overall Budget](#)
- [Agency Fact Sheets](#)

- [Key Issues Fact Sheets](#)

## **Science on the Campaign Trail: Where the Presidential Candidates Stand**

The 2016 presidential election season is underway as voters have cast their first ballots at the Iowa caucuses and the New Hampshire primary. Science-related issues have not yet gotten much attention from the candidates, as the debate has been dominated by national security, immigration policy, and the economy, but we hope it will increasingly. [Here](#) is a broad overview of where all the candidates stand on some select science-related issues (keeping in mind that the candidates have yet to sound off on many topics of interest to researchers) put together by *Science Insider*. Please note: the Endocrine Society is non-partisan and does not endorse political candidates.

## **Clinical News**

### **Society Advocates for Revaluation and Redefinition of E&M Codes**

The Endocrine Society helped create a new coalition of cognitive specialists, the Cognitive Care Alliance, to further advance our work to ensure that endocrinologists are adequately reimbursed for their work. Over the past few weeks, the coalition has met with key officials in federal agencies and on Capitol Hill to discuss the need for new outpatient Evaluation and Management (E&M) codes to address the expertise of cognitive specialists in effectively diagnosing and treating diseases. Specifically, the coalition has met with Mark Miller, Executive Director of the Medicare Payment Advisory Commission; Sean Cavanaugh, Director of Medicare at the Centers for Medicare and Medicaid Services; and key staff from the Senate Finance Committee, who acknowledged that cognitive specialists face related to reimbursement. We will continue to work with the Society's Clinical Affairs Core Committee and will keep our members informed as we move forward to address this important issue.

### **CMS Provides Instruction for Submitting Expedited MU Hardship Applications**

As previously reported in *Endocrine Insider*, Congress granted the Centers for Medicare and Medicaid Services (CMS) the authority to expedite applications for exemption from Meaningful Use (MU) Stage 2 requirements for the 2015 calendar year. CMS has posted new, streamlined hardship applications, reducing the amount of information that eligible professionals (EPs), eligible hospitals, and CAHs must submit to apply for an exception. The new applications and instructions for a hardship exception from the Medicare Electronic Health Records Incentive Program 2017 payment adjustment are available on the [CMS website](#).

EPs who wish to use the streamlined application must submit their application by March 15, 2016, and eligible hospitals and critical access hospitals must submit their application by April 1, 2016.

Unlike previous years, groups of providers are now able to apply for hardship exception on a single application. Under the group application, multiple providers and provider types may apply together using a single submission. The hardship exception categories are the same as those applicable for the individual provider application. Providers will have the option to submit an electronic file (in excel or csv formats) with all National Provider Identifiers (NPIs) or CMS Certification Numbers (CCNs) for providers within the group or use a multiple NPI or CCN form to submit their application.

### **Society Asks FDA to Consider Distinguishable Names and Comprehensive Labeling for Biosimilars**

On February 9, the U.S. Food and Drug Administration (FDA) met with its Arthritis Advisory Committee to discuss a proposed biosimilar, Remsima, the second biosimilar that is likely to be approved in the U.S. The Society, in conjunction with the Biologics Prescribers Collaborative, submitted [comments](#) to the Advisory Committee in support of the FDA's commitment and deliberation on biosimilar-related issues. The comments acknowledged the growing complexity of the treatment landscape and requested that the FDA consider the following factors as bio-similar related policies are implemented:

- Biological products should have distinguishable, non-proprietary names.
- Biosimilar product labeling should contain all necessary data for physicians to make appropriate prescribing decisions.
- Requests for indication extrapolation should be considered with caution.

The Society looks forward to continuing to work with the FDA as it reviews new applications for biosimilars to ensure that these products are named and labeled appropriately.

### **Deadline Extended – Apply Now for the 2016 Harold Vigersky Practicing Physician Travel Award**

Apply today for the 2016 [Harold Vigersky Practicing Physician Travel Award](#). Named for Past-president Robert Vigersky's father, the award assists clinical practitioners operating in private practice by offsetting the cost associated with attending the Endocrine Society's annual meeting ([ENDO](#)) or Clinical Endocrinology Update ([CEU](#)).

The award recipient will receive complimentary registration to either ENDO or CEU and a \$1,500 allowance for travel and lost productivity. Physicians working in private practice who are not reimbursed for travel to clinical meetings or CME conferences are encouraged to apply. Specific eligibility requirements apply and can be found with the online application form on [the Society's website](#).

Applications are accepted through **Monday, February 22**.

## **Research News**

### **NIDDK Advisory Council Discusses New Advances, Budget Increase**

On January 27, Endocrine Society staff attended the 200th meeting of the National Diabetes and Digestive and Kidney Diseases (NIDDK) Advisory Council. Society members Lee Kaplan, MD, PhD; Alan Saltiel, PhD; Jerry Palmer, MD; and Joel Elmquist, PhD, DVM, are members of the Council, which advises the Director of the NIDDK on research, support activities, and functions of the Institute. Endocrine Society member Steven Kahn, MB, CHE, served as an ad hoc Council member for this meeting.

During the open session of the meeting, the Director of NIDDK, Dr. Griffin Rodgers, announced the publication of [Recent Advances & Emerging Opportunities 2016](#). This report, issued annually, highlights important advances and discoveries that resulted from NIDDK funded research over the previous fiscal year. Dr. Rodgers then gave the Council an update on the NIDDK budget process, including the additional funds provided by the omnibus appropriations bill for FY 2016. The NIDDK expects that the regular R01 payline will be maintained at the 13th percentile, with grants requesting over \$500,000 in direct costs having a payline of 8 percent. Early stage investigators (ESIs) will have a differential payline of 18 percent, while first competitive renewal applications of R01 grants awarded to NIDDK ESIs will have a payline of 15 percent.

The Advisory Council was then joined by the Director of the National Institute on Minority Health and Health Disparities (NIMHD), Eliseo Perez-Stable, MD, and the Director of the National Institute on Neurological Disorders and Stroke (NINDS), Walter Koroshetz, MD. Dr. Perez-Stable described the mission of the NIMHD and the need to appropriately distinguish research on minority health, health disparities, and inclusion; all of which are important domains but need to be treated separately. He then discussed the need to properly define health outcomes and health differences, and stressed the importance of health services research as a priority. Dr. Koroshetz then gave the Council an update on NINDS' budget process, and strategies the Institute has pursued to maintain a payline at the 15th percentile. He also indicated that NINDS

would issue a Request for Applications to generate more applications for fundamental, basic research.

During the open session of the Diabetes, Endocrinology and Metabolism (DEM) Subcommittee, Council members discussed initiatives that NIDDK might pursue. NIDDK staff presented potential initiatives on: circadian biology, sleep and diabetes; clinical studies of diabetic foot ulcers; sleep apnea, glycemia, and type 2 diabetes; and type 2 diabetes prevention and management. The Council gave advice on key focus areas and priority topics for these proposed initiatives.

### **White House Seeks Microbiome Science Champions**

On January 27, the White House Office of Science and Technology Policy (OSTP) issued a call to action for “new commitments to microbiome research from all sectors.” The call to action seeks examples of new research that individuals or institutions are pursuing to better understand the microbiome, such as:

- The development of interdisciplinary centers that support projects tackling fundamental, cross-cutting questions and themes related to microbiome science.
- The development of platform technologies, reference libraries, and databases useful for microbiome research in all habitats.
- Grants, fellowships, internships, and cluster hires that promote interdisciplinary microbiome work among faculty and students.

**Take Action:** We encourage interested members of the Endocrine Society working on the microbiome to respond to the call to action. For additional information, please see the [OSTP announcement](#), or fill out the [web-based form](#).

### **CSR Examines NIH Impact of Budget Boost and Peer Review; New Biosketch Tips**

The NIH Center for Scientific Review (CSR) publishes a [quarterly newsletter, Peer Review Notes](#), “to inform our reviewers, NIH staff and others of news related to our grant application review policies, procedures and plans.” In the January edition of Peer Review Notes, CSR updated readers on the impact of the \$2 billion increase for NIH in the FY 2016 omnibus appropriations bill. The article notes that the roughly 6 percent increase in funding may not have an appreciable impact on grant success rates, given the increase in applications received by the NIH in FY 2015, which is expected to persist into FY 2016 and beyond. The Director of CSR, Dr. Richard Nakamura, noted that CSR struggles to recruit grant reviewers and appealed to applicants to “develop and submit

applications as their research and ideas justify the effort to write them” and to research deans to avoid forcing PIs to submit grants regularly to fulfill quotas.

The newsletter also contains a list of tips for applicants and reviewers regarding the new biosketch, introduced in May and now required on all grant applications. The Endocrine Society has previously [expressed concern](#) with the modified biosketch format, and we encourage members to examine Peer Review Notes and other resources on the [CSR webpage](#) for help adapting to the new format.

### **Endocrine Research Questions Safety of BPA Alternatives**

The Endocrine Society’s global endocrine disrupting chemicals advocacy program seeks to ensure that regulators systematically evaluate chemicals, and their replacements, for their potential effects on the endocrine system. In response to research showing that bisphenol-A (BPA) can disrupt the endocrine system, manufacturers have substituted BPA with similar chemicals, such as bisphenol-S (BPS). However, emerging research suggests that replacements for BPA may have similar endocrine disruptor properties. A recent study from a team of researchers at UCLA and Shanghai University, published in [Endocrinology](#), demonstrated similar effects on zebrafish exposed to either BPA or BPS. The study was reported by many news outlets, including [the Washington Post](#) and [Yahoo](#).

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within the Endocrine Society, contact the Government & Public Affairs department:

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