September 15, 2016

Advocacy News

Funding Decisions Coming Down to the Wire; Take Action Today to Support NIH

Lawmakers face an October 1 deadline to pass a funding bill to avoid a government shutdown. Recent discussions among Congressional leaders increase the likelihood that Congress will pass a short-term continuing resolution (CR) to fund the government at current levels through December 9.

This is a positive development for the biomedical community as a short-term CR means that Congress could still pass appropriations bills that include a $2 billion increase for the National Institutes of Health (NIH) before the end of this year. Under a long-term CR, NIH will not fund new projects and likely will not release the full amount of awarded grant funds.

The Senate is expected to consider the CR this week after which it will send the bill to the House for consideration. The biggest obstacle is the addition to various policy riders from Zika control to Planned Parenthood funding. The Senate plans to leave town after its vote, which means that the House will either have to pass the bill as-is or risk shutting down the government.

Take Action:

* E-Action Alert: All Endocrine Society members are strongly encouraged to participate in our online advocacy campaign to urge Congress not to adopt a long-term CR and to focus on passing an omnibus spending bill, including an increase for NIH. Taking action is quick and easy. Click to access the campaign, and a pre-written letter will be provided for you. You will only need to either provide your email and member ID, OR enter your address information so that the system will send your message to the correct recipients.

* NIH Advocacy Toolkit: We have provided Society members with several ways to share our message about the importance of NIH funding. Our toolkit includes information to help Society members use social media, write op-ed articles, share their story, etc. Please visit the NIH Advocacy Toolkit today.

* Rally for Medical Research: Members of the Advocacy and Public Outreach Core Committee will be coming to DC to participate in a Rally for Medical Research with other members of the research community on September 22. We will be visiting Members of Congress and urging them to support NIH.

Endocrine Society Advocacy Delays MACRA Payment Penalties

On September 8 Acting Administrator of the Centers for Medicare and Medicaid Services (CMS) Andy Slavitt announced that the final Medicare Access and Chip Reauthorization Act (MACRA) regulation will exempt clinicians and other healthcare providers from any risk of penalties in their 2019 payments if they choose one of three reporting models for the Merit-based Payment Incentive Program (MIPS) in 2017.

- Full-year reporting that begins on January 1;
- Partial year reporting for a reduced number of days; and
- A "test" option under which physicians can report minimal amounts of data.

Those who choose to report for the full year or partial year may be eligible for bonus payments of a "modest" or "small" amount in 2019; clinicians and other providers who choose any of the three reporting options will not be subject to payment adjustments. Qualified participants in advanced APMs will still be eligible for the 5 percent payment incentive in 2019.

This is a significant improvement to the proposed rollout of the new payment system that was a direct result of ongoing advocacy efforts by our Society, the American Medical Association, other clinician organizations, and clinician and other providers across the country. A delay in the reporting period was the top priority in our June 26 comments on the MACRA proposed rule and subsequent advocacy.

We applaud the Administration for listening to the concerns of those who will be most directly impacted by the new payment system and look forward to continued collaboration as MACRA is implemented.

FDA Bans EDCs from Antibacterial Soaps

On September 2, the United States Food and Drug Administration (FDA) issued a final rule on the safety and effectiveness of antibacterial soaps. The rule states that active ingredients in over-the-counter consumer antiseptic washes "are not generally recognized as safe and effective (GRAS/GRAE) and are misbranded." The endocrine-disrupting chemicals (EDCs) triclosan and triclocarban were among the 19 ingredients that are banned by the final rule, effective September 6, 2017.

The FDA noted that there is no scientific evidence supporting the hypothesis that the chemicals used in antibacterial soaps are more effective than regular soap and water. Consistent with the Endocrine Society's longstanding position on EDCs and our comments to the FDA, the FDA noted that triclosan and triclocarban could pose health risks, including hormonal effects. Many of the potential health effects of triclosan were summarized in the Endocrine Society's Scientific Statement on EDCs.

The Endocrine Society applauds the FDA's decision on antibacterial soaps and we appreciate the agency's recognition that the chemicals used in these products "may do more harm than good over the long term." We will continue to work with the FDA on reducing the risks of harms due to exposure to EDCs in consumer products, such as personal care products.

Take Action: As mentioned previously in *Endocrine Insider,* Senators Dianne Feinstein (D-CA) and Susan Collins (R-ME) have introduced the Personal Care Products Safety Act (S. 1014), which would amend the Federal Food, Drug, and Cosmetic Act to allow the FDA to collect information on ingredients in personal care products and prohibit distribution of a personal care product if it could cause serious adverse health consequences. The bill would also require the FDA to review the safety of at least 5 ingredients each year. Joining our campaign to support this bill is quick and easy. Click to access the campaign, and a pre-written letter will be provided for you. You will only need to either provide your email and member ID, OR enter your address information so that the system will send your message to the correct recipients.

Society Comments on 2017 Medicare Physician Fee Schedule

The Centers for Medicare and Medicaid Services (CMS) released the 2017 Medicare Physician Fee Schedule proposed rule which recommends changes to physician payment policies for the upcoming year. The Society provided comments to CMS on issues of importance to

endocrinologists, including improving payment accuracy for primary care, care management services, coverage of the National Diabetes Prevention Program, and utilization of diabetes self-management training services.

Our comments recognized the importance of researching evaluation and management (E/M) codes to ensure that cognitive specialists are properly compensated for the services they provide. Current global periods assume that E/M services provided in global periods are similar to that provided by cognitive specialists in an office setting. The Society noted that the care required by a patient recovering from a procedure is fundamentally different from the typical follow-up of an established outpatient, especially when dealing with a patient with diabetes and other co-morbidities. Because of this, we supported CMS' proposal to conduct research that may make this delineation.

In the proposed rule, CMS also proposed to make separate payments for non-face-to-face prolonged evaluation services. The Society applauded CMS for this proposal and reiterated that the existing E/M services do not appropriately reflect and reimburse the non-face-to-face care required by endocrinologists who treat patients with chronic illnesses. However, the Society stated that it views this as a temporary solution until cognitive E/M services can be properly evaluated. We were also concerned that CMS is requiring for these services to be billed on the same day as an E/M service as it would limit the utilization of this code and fail to account for care needed between office visits.

Finally, the Society was pleased that CMS recognized the needs of patients with diabetes in its proposal to provide coverage for the National Diabetes Prevention Program (DPP) and in requesting additional information about barriers for the utilization of diabetes self-management training (DSMT) services. The Society has been working with federal agencies and stakeholders to attain coverage for the DPP and is encouraged that CMS has recognized the benefit of the program in preventing diabetes. We were also pleased that CMS has requested additional information on barriers for DSMT utilization and looks forward to working with the agency to rectify this growing problem.

CMS will finalize its rule in November 2017. The Society will inform its members once the rule becomes final in November and which recommendations have been finalized.

Clinical News

Endocrine Society Launches MACRA Webpage

The passage of the Medicare Access and Chip Reauthorization resulted in an entirely new payment system that reimburses clinicians based on value rather than volume. Many practices will have to make significant changes to the way they provide care in order to avert payment penalties.

We have launched a new webpage designed to provide our members with a one-stop shop for resources to help with the transition to the new payment system. The recent Clinical Endocrinology Update meeting included a session that provided attendees with a comprehensive overview of MACRA; the recording of this session is available on the MACRA webpage.

For questions about the program or to suggest additional resources to include on the webpage, members can contact Stephanie Kutler, Director, Advocacy & Policy at skutler@endocrine.org.

USPSTF Clarifies Diabetes Screening Recommendations

Last October, the U.S. Preventive Services Task Force (USPSTF) released new screening recommendations for diabetes which dramatically expand access to individuals with abnormal blood glucose and for those who may be at risk. These recommendations enable physicians to screen patients who are over 40 years old with no obvious symptoms of diabetes and those individuals under 40 who have a family history or who are of a certain ethnic/racial background. The Society was concerned that the final recommendations were difficult to interpret and do not provide clear guidance on who should be screened. We met with the USPSTF and other federal agencies, in conjunction with other diabetes stakeholders, to discuss these concerns and requested the development of an FAQ for use in primary care settings. The USPSTF was very receptive to these concerns and revised its website to include more straightforward guidance on its recommendations. The Society has also worked with the Diabetes Advocacy Alliance to develop a fact sheet on what these recommendations mean and who is eligible for screening.

Recall on GlucaGen HypoKit Due to Detached Needles on Syringe

Novo Nordisk has issued a recall for six batches of the GlucaGen HypoKit in the United States due to detached needles on the syringe. This defect renders the devices unusable as prescribed, thus putting patients with hypoglycemia at risk of experiencing a hypoglycemic episode.

The recall includes GlucaGen HypoKit batch numbers:

- Batch: FS6X270, Expiry: 09/30/2017
- Batch: FS6X296, Expiry: 09/30/2017
- Batch: FS6X538, Expiry: 09/30/2017
- Batch: FS6X597, Expiry: 09/30/2017
- Batch: FS6X797, Expiry: 09/30/2017
- Batch: FS6X875, Expiry: 09/30/2017

While a small number of needles (0.006%) are said to be defective, patients and caregivers who purchased this product on or after February 15, 2016 are advised to check the batch number to see if their GlucaGen HypoKit is affected. The batch number can be found below the expiry date, as seen in the FDA's product photos.

If you have an affected GlucaGen HypoKit, please call 888-840-1137 from Monday to Friday (8:30am - 6:00pm EST) to find out how to return the product. Healthcare professionals and patients are also encouraged to report adverse effects from a GlucaGen HypoKit to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Research News

Endocrine Society Participates in Workshop on Nonhuman Primate Research

On Wednesday, September 7, 2016, the National Institutes of Health (NIH) held a workshop to explore the state of the science using nonhuman primates (NHPs) and to review existing ethical oversight of NHP research. The workshop was organized in response to a Congressional request asking NIH to "conduct a review of its ethical policies and processes with respect to nonhuman

primate research subjects, in consultation with outside experts, to ensure it has appropriate justification for animal research protocols." The workshop consisted of two sessions; 1) the state of the science of NIH-supported research involving NHPs, and 2) the existing ethical framework for research on NHPs.

Endocrine Society Past-President, Dr. Teresa Woodruff, PhD, delivered a presentation about "why NHPs are critical in reproductive research and translative medicine". Dr. Woodruff's presentation described landmark discoveries and critical advances in reproductive health based on research in NHPs, including insights on the risks and benefits of medications. She also highlighted scientific advances due to research with NHPs in fields such as:

- Disease, including polycystic ovarian syndrome (PCOS)
- Assisted reproductive technology, including the first proof of concept studies for therapeutic cloning
- Imaging techniques to help understand placental biology
- Fertility, for example in restoring reproductive function after cancer treatment

Other speakers commented on the role of NHPs in understanding infectious disease, brain research, and recovery from heart attack. The second session included presentations on the laws and ethical framework governing animal research, cost-benefit relationships for research on NHPs, the perspective of veterinarians, and principles governing animal use protocols.

The Endocrine Society also recently worked with the Foundation for Biomedical Research (FBR) on the development of a white paper, *The Critical Role of Nonhuman Primates in Medical Research*. The white paper is a collaboration between FBR and eight premier scientific groups: the American Academy of Neurology, the American College of Neuropsychopharmacology, the American Physiological Society, the American Society for Microbiology, the American Transplant Foundation, the Endocrine Society, the Federation of American Societies for Experimental Biology and the Society for Neuroscience. The white paper highlights the essential role NHPs historically have and continue to play in finding treatments for serious and life-altering conditions such as Alzheimer's disease, cancer, Zika virus, HIV/AIDS and Parkinson's disease.

For more information on the workshop, or to see a recording of the event, please see the archived webcast.

NIEHS Requests Input on Translational Research Framework

On September 13, the National Institute of Environmental Health Sciences (NIEHS) issued a Request for Information (RFI) seeking input on a draft translational research framework for environmental health research. The feedback received via the RFI will be used to "further inform and finalize the framework."

NIEHS welcomes responses from environmental health researchers, as well as other stakeholders with an interest in environmental health science or experience creating and using translational research frameworks to evaluate research. Respondents are specifically asked for comments in the following areas:

- Applicability of the proposed translational research framework map to your translational research in environmental health sciences.
- Benefits and/or challenges related to recognizing movement both around a translational research "ring" as well as across translational research "rings" as translational.
- Elements of translational research in environmental health science that are missing from the framework.
- Suggestions for other names of the framework components.
- Other comments on the utility of this framework for guiding, managing or evaluating translational research.

For more information on the RFI, including instructions on how to submit your comments, please see the full notice on the NIH Grants Website. Please note that the deadline for responses is October 30, 2016.

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:

Mila Becker, Chief Policy Officer
202-971-3633
Mbecker@endocrine.org

Aaron Lohr, Director, Media Relations
202-971-3654
Alohr@endocrine.org

Jenni G. Gingery, Associate Director, Media Relations
202-971-3655
Jgingery@endocrine.org

Jessica Harris, Specialist, Government & Public Affairs
202-971-3660
Jharris@endocrine.org

Stephanie Kutler, Director, Quality Improvement
202-971-3635
Skutler@endocrine.org

Meredith Dyer, Associate Director, Health Policy
202-971-3637
Mdyer@endocrine.org

Joseph Laakso, PhD, Associate Director, Science Policy
202-971-3632
Jlaakso@endocrine.org