November 30, 2017

Advocacy News

Congress' Christmas List is a Huge Challenge; Health Care Topics Figure Prominently in Year-End Legislation

As this issue of *Endocrine Insider* goes to press, the end of year "To Do" list for the US Congress keeps growing and getting more complicated. Before the end of the year Congress needs to enact:

- Budget deal to raise the budget caps
- Final FY 2018 spending legislation (or another short-term spending bill to buy more time and prevent a government shut-down)
- Disaster funding
- Reauthorization of the Children's Health Insurance Program along with reauthorization of the Special Diabetes Program, Community Health Centers, and National Health Service Corps
- Tax reform (a political must-do)
- Stabilize health insurance markets
- Fix the Deferred Action for Childhood Arrivals (DACA) Act

Enacting any one of these items would be a big deal. Taken together, in the short time remaining before the end of the year, policy analysts predict it will take a Christmas miracle to achieve. For endocrinology, the list is notable because health care topics figure prominently in the year-end legislative measures, the fate of some specific federal programs like the Special Diabetes Program and funding for the National Institutes of Health (NIH) is unclear, and other measures could significantly impact endocrinologists, researchers, and patients like the tax reform bill's removal of the individual mandate and waiver for graduate student tuition.

Below is a summary of the legislation the Society is working on and ways for you to get involved and take action:

- NIH Funding – Although Congress is supposed to finalize funding for the new fiscal year by October 1, it was not able to do so and instead put into place a short-term spending bill to keep the government running at current funding levels through December 8. The main reason a deal was not possible was because to provide funding increases, Congress will need to raise the budget caps currently in law. While some lawmakers remain optimistic that another short-term spending bill running into next year will not be necessary, top appropriators and senior congressional staff report that congressional leaders have little hope of striking a deal on spending caps before December, setting up another stopgap funding measure after the current one expires December 8. Consequently, funding for NIH, a top priority for the Society, remains in jeopardy.

Take Action: All US Society members interested in research are encouraged to join the Society's online advocacy campaign urging Congress to raise the budget caps and provide an increase in NIH funding, even if you have taken action before. Taking action is quick and easy. Simply visit www.endocrine.org/advocacy, select the Support NIH campaign and enter EITHER your home address OR your email and member ID. A sample letter is provided, which you can personalize if you choose to, and our software will direct the letter to your congressional delegation.

- Special Diabetes Program – Another issue of interest for the Endocrine Society is continuing funding for the Special Diabetes Program (SDP). SDP is actually comprised of two programs: the Special Type 1 Program that funds NIH research and the Special Diabetes Program for Indians that provides diabetes education and prevention programs for American Indians and Alaska Natives. Congress let funding for the Special Type 1 Program expire October 1 and funding for the SDPI will expire on December 31 if Congress fails to act. The Senate is currently considering the extension of a number of healthcare programs as part of the Children's Health Insurance Program (CHIP) reauthorization.

Take Action: We need all US members who treat people with diabetes or research on Type 1 to contact the Senate NOW to ensure both SDP programs are included in any healthcare extenders bill. Visit www.endocrine.org/advocacy, select the SDP campaign and enter EITHER your home address or your email and member ID to contact Congress about this important program.

- Tax Reform – The congressional tax reform effort is the immediate issue on the agenda in Washington with President Trump pushing hard to get a deal passed by Christmas. The tax

overhaul contains many provisions, but health care topics figure prominently in the legislation and the Society is working on several items that directly affect endocrine researchers, clinicians, and patients:

- The Senate version would remove the health insurance mandate penalty, a cornerstone of Obamacare, to provide savings that could be applied to offset other contentious tax issues, but also increases premiums and the number of uninsured. The Society has consistently opposed any measure that would increase the number of uninsured or access to affordable coverage and we joined as the only endocrine-related organization with the Trust for America's Health, public health, medical societies, and patient advocacy groups in sharing our concerns with Congress.
- The House version would eliminate the exemption for tuition waivers from taxable income for graduate students who serve as teaching or researching assistants. The Society has joined the March for Science and FASEB in opposing this provision arguing that taxing tuition waivers for graduate students will create a financial hardship for individuals who typically have modest incomes and providing tuition remission allows universities and colleges to reduce the cost of graduate education or students who teach or conduct research as part of their training.
- The House version would also eliminate the current deduction for student loan interest and the deduction allowed for medical expenses.

The House of Representatives passed its version of tax reform last month; the Senate is planning to vote on its version November 30 although it is still unclear whether the Senate will have a majority to pass it. The biggest challenge for Republicans is that the measure would increase the deficit by an estimated $1.5 trillion. The deficit increase would trigger a budgetary law, known as PAYGO, which begins across the board spending cuts. Medicare would be liable for $25 billion in cuts. Congress normally inserts budget rule waiver language into year-end legislation to avoid automatic cuts, however, this sets up an awkward quandary for Members of Congress of allowing either Draconian spending cuts or a dramatic deficit increase.

To stay up to date on the latest congressional actions and Society advocacy, please look for updates on Endocrine News online and Society advocacy alerts.

Society Collaborates with Patient Advocacy Group to Introduce PCOS Resolution in Senate

On November 16, Senators Elizabeth Warren (D-Mass.) and David Perdue (R-Ga.) introduced a bipartisan resolution that would recognize September 2018 as "Polycystic Ovary Syndrome Awareness Month". The resolution (S.Res.336) acknowledges the seriousness of PCOS and calls for increased awareness of the disorder, better diagnosis and treatment, further research, and improving the quality of life for affected women. A House version of this resolution was introduced earlier this year.

The Society has been working with PCOS Challenge, a PCOS patient advocacy group, to raise awareness about the disorder and its challenges. Earlier this year, PCOS Challenge hosted a Congressional briefing, and staff from both associations have met with several Congressional offices to educate them about PCOS and ask for their support. The Society will continue to work with PCOS Challenge and Congress to pass the resolution.

Amicus Brief Influences Decision in *Doe v. Trump*

Earlier this year, President Trump announced that "the United States Government will not accept or allow transgender individuals to serve in any capacity in the U.S. Military." Prior to the Presidential Memorandum, the Department of Defense had announced that openly transgender individuals would be allowed to enlist beginning January 1, 2018.

Numerous plaintiffs, current and aspiring service members who are transgender, brought a suit against the Administration seeking an injunction of the Presidential Memorandum. On October 30, 2017 the U.S. District Court for the District of Columbia ruled in favor of the plaintiffs in *Doe v. Trump* and issued a preliminary injunction that prohibits the Administration from banning transgender people from enlisting and serving in the military.

As endocrinologists are one of the most important members of a transgender individual's care team, the Endocrine Society has prioritized work to ensure that transgender individuals have access to care, regardless of the setting. Based on this, the Society has joined 11 leading medical, nursing, mental health, and other health care organizations on Amicus Briefs for numerous court cases focused on the rights of transgender individuals, including *Doe v. Trump*. The brief in this case was cited favorably by the judge numerous times in the court's memorandum opinion.

Our work on transgender health issues is based on the Society's November 2017 Clinical Practice Guideline, Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, and September 2017 position statement on Transgender Health.

Clinical News

AMA Advances Society Policy Priority on Insulin Pricing and Other Clinical Issues

The American Medical Association (AMA) House of Delegates met in early November to establish policy positions on topics of importance to patients and health care providers. The meeting provides the opportunity for organizations like the Society to gain support for a policy priority from the House of Medicine.

The Endocrine Society teamed up with the American Association of Clinical Endocrinologists (AACE) to introduce a resolution that urged the AMA to pursue several initiatives aimed at improving insulin affordability for patients with diabetes. The resolution called on the AMA to convene a summit to identify potential solutions to the dramatic increase in insulin costs and also advocate for initiatives to reduce patient cost-sharing for insulins, stabilize drug formularies throughout a plan year to reduce non-medical switching of insulin products; facilitate greater transparency of insulin pricing and integrate drug formularies into electronic health records. Overwhelming support for addressing insulin costs and their impact on patients expressed on the floor of the House of Delegates led to a unanimous vote for the AMA to study these issues and provide a report with findings and recommendations to the House of Delegates at the 2018 Annual Meeting in June.

The Society also introduced a resolution, co-sponsored by AACE and the American Society for Reproductive Medicine, in response to the Rule released in October by the Department of Health and Human Services that would expand the companies that are eligible for an exemption based on moral or religious exemptions from the requirement to provide contraception at no-cost to their employees. The resolution called on the AMA to work to halt the implementation of the Rule to ensure that all women continue to have access to preventive contraception. The House of Delegates reaffirmed its commitment to this issue based on existing policy.

Policies were also established at the House of Delegates meeting that address other Society policy priorities, including access to preventive screening tests for transgender individuals, health insurance coverage, and prescription drug pricing.

FDA Launches CE for Healthcare Providers to Reduce Hypoglycemic Events

The U.S. Food and Drug Administration (FDA) is making available a free, one-hour continuing education (CE) lecture for healthcare providers on Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes. With hypoglycemia from anti-diabetic medications, such as insulin, being the second most common adverse drug event implicated in emergency department visits, it is critical for healthcare providers to recognize risk factors, such as low health literacy and numeracy, cognitive decline, and food insecurity, and know how to mitigate these risks to improve patient outcomes. The course introduces and provides healthcare providers with printable tools that they can use with their patients and will be available on the CDERLearn website (under Continuing Education Courses) until October 31, 2020.

Quality Payment Program Rule Finalizes Structure for 2018; Cost Measurement to Be Included

On November 2, 2017, the Centers for Medicare and Medicaid Services (CMS) released its final rule outlining the requirements for year two of the Quality Payment Program (QPP). The QPP includes two tracks for participation in 2018: the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs).

CMS finalized the majority of the policies outlined in the proposed rule released earlier this year and modified several others. Some of the key policies finalized include the following:

- Cost will count toward the MIPS composite score in the 2018 performance year unlike in the first year of MIPS
- Improvement scoring in the Quality and Cost performance categories was implemented
- A new bonus point opportunity for clinicians who treat complex patient populations, based on a combination of Hierarchical Condition Categories (HCCs) and the dual eligible population treated

- An increase in the low-volume threshold to less than or equal to $90,000 in Medicare Part B allowed charges **or** less than or equal to 200 Part B patients
- Implementation of a virtual group option starting in the 2018 performance year
- Implementation of the "All-Payer Combination Option" for the Advanced APM pathway starting in the 2019 performance year, with Medicare Advantage models applying to the All-Payer option

Additional information on the QPP program can be found on the Society's QPP webpage.

Research News

NIH Continues Implementation of Updated Clinical Trial Policy

On November 7, the National Institutes of Health (NIH) issued Parent Announcements (PAs) for R01 and R21 Research Project Grant applications that have been updated to reflect the new definition for clinical trials. As reported previously in *Endocrine Insider*, the NIH is updating policies for clinical trials such that they are consistent with the new definition of a clinical trial, i.e., "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

Updates to the new policies will take effect for grants with application due dates in January. However, not all NIH Institutes and Centers participate in the Parent Announcements, and some Institutes will accept only mechanistic trials that meet the new definition (see, for example, NIAMS NOT-AR-18-008 and NHLBI NOT-HL-17-546.)

We encourage members of the Endocrine Society who conduct research with human subjects to carefully examine the Parent Announcements and contact your Program Officer for guidance on whether the updated definition of a clinical trial will affect your research. The NIH has developed resources to assist researchers who may be impacted, including:

- A Decision Tool
- Video Tutorial
- Case Studies
- Frequently Asked Questions

NIH Announces That Project Outcomes Section of RPPRs Will be Publicly Available

On November 16, the NIH announced their intention to publish the Project Outcomes section of all final and interim research performance progress reports (RPPRs) submitted on or after October 1, 2017. The Project Outcomes sections will be publicly accessible via the NIH Research Portfolio Online Reporting Tools (RePORTER) website. The intent of the new policy is to provide transparency and allow taxpayers to understand the value of the research that is funded by the government.

While the NIH will only publish project outcomes "that have been reviewed and approved by NIH staff to ensure the narrative is written for the general public in clear and comprehensible language", outcomes will be published exactly as they are submitted by the grantee. According to the NIH Extramural Nexus Open Mike blog, this means that the outcomes section should be written at a 10th Grade level. Grantees are asked to not include confidential or proprietary information in the Project Outcomes section.

For additional information, we encourage Endocrine Society members to examine the RPPR web page, FAQs, and tips on using plain language.

NIH to Require Analysis of Sex/Gender, Race, Ethnicity in Phase III Clinical Trials

On November 28, the NIH issued a notice to inform the research community that grantees conducting applicable Phase III clinical trials should ensure that "results of valid analyses by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov." The notice will amend the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, and applies to grants awarded on or after December 13, 2017.

For more information on the scope and applicability of the policy, as well as guidelines for reporting results, please see the detailed announcement at the NIH Grants Guide.

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, Chief Communications Officer
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, Advocacy and Policy
202-971-3635
Skutler@endocrine.org

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

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