
**February 25, 2016**

## Advocacy News

### Supreme Court Vacancy Could Lead to Even More Gridlock

Congress could be headed for an unprecedented level of gridlock as the Senate faces a bitter fight over replacing the late Supreme Court Associate Justice Antonin Scalia.

Shortly after Scalia's death was announced, Senate Republican leaders said they would not move forward on any nominee put forward by President Barack Obama. But while Democrats cannot schedule hearings or votes on a nominee, they do have their own options. Even with Republicans in control of both chambers for this Congress, Democrats can block virtually anything they want from coming to a vote and that could disrupt the GOP's strategy to show that the Senate "is working again" by approving all of its appropriations bills in an orderly fashion this year.

Last year, for example, Democrats signaled they would block any appropriations bill that adhered to the automatic, across-the-board spending cuts known as sequestration. Despite repeated attempts by Republicans to bring up spending bills, Democrats moved to impede their progress to the floor, holding out until they got a budget deal they could live with in October. That paved the way for a year-end spending package in December that lifted those spending restrictions and increased funding for the National Institutes of Health (NIH) by $2 billion.

This week, Congress returned to Washington from a recess with budget process considerations on the top of the agenda. Democrats made clear that they are prepared to wage war over Senate Majority Leader Mitch McConnell's (R-KY) refusal to consider any nomination to the court. This means the budget and appropriations process could grind to a halt almost as soon as it starts. By that measure, the impact of Justice Scalia's death may be felt well beyond the Supreme Court.

**Where We Stand:** The Endocrine Society continues to advocate for increased federal funding for biomedical research and is calling for $35 billion for the NIH. As we head into the scheduled budget and appropriations season, the Society is a leader in several coalitions organized to support increased funding for federal agencies, including the NIH, the Veterans Administration, and the Centers for Disease Control and Prevention. Society members are also coming to Washington to participate in congressional visits to educate Members of Congress about endocrine-related research. As Congress gets closer to possible action, the Society will send a legislative alert to members.

**Senate Begins Consideration of Innovations Bill; Endocrine Society Advocates for Inclusion of Female Subjects in Pre-Clinical Research**

The Senate Health, Education, Labor and Pensions (HELP) Committee has begun discussions on legislation that will be combined to form the Senate's Medical Innovations bill. The Innovations bill will be the Senate's version of the House-passed 21st Century Cures (HR 6) legislation and aims to enhance research at the National Institutes of Health, improve the approval process of new drugs and devices at the Food and Drug Administration, and address concerns of the medical community on electronic health systems.

The first component of the Medical Innovations is consideration of legislation focused on the use of medical technology to improve care and the health care system. Building on what was learned during a series of Senate hearings held in 2015 on health information technology (HIT), Senators Lamar Alexander (R-TN) and Patty Murray (D-WA) introduced the Improving Health Information Technology Act (S. 2511). The legislation, which the HELP Committee voted to incorporate into the Innovations bill, will ease some of the administrative burdens associated with the technology and help providers select quality products.

In line with these goals, Medical Innovations also would ease FDA approval requirements for the makers of certain drugs and devices to streamline the process for demonstrating the effectiveness and efficacy. While calls to reduce these burdensome requirements is mellifluous to the medical device industry, information on which drugs and devices would be included remains unknown. The Society has supported refinements to the FDA approval process, including the utilization of a parallel review process with CMS to improve access to new diabetes therapies. We believe that this type of collaboration could lead to more rapid development of CMS coverage policies and funding for new technologies.

Chairman Alexander and Ranking Member Patty Murray are still negotiating the potential inclusion of mandatory funds for NIH as a component of the Medical Innovations package. However, several of the individual bills currently up for consideration could also affect researchers. The Advancing Research for Neurological Diseases Act (S. 849), sponsored by Senators Isakson (R-GA) and Murphy (D-CT) would require the Department of Health and Human Services to facilitate research on neurological diseases through the use of a new National Neurological Diseases Surveillance System, run by the Centers for Disease Control. The Next Generation Researchers Act (S. 2014), sponsored by Senators Baldwin (D-WI) and Collins (R-ME) would create a new office within the NIH Office of the Director to coordinate NIH policies for new researchers. And the Enhancing the Stature and Visibility of Medical Rehabilitation Research at the NIH Act (S. 800), sponsored by Senators Kirk (R-IL), Bennett (D-CO), Hatch (R-UT), Murkowski (R-AK), Isakson and Collins, would set expectations for rehabilitation research planning at NIH and subsequent annual reporting to Congress.

**Where We Stand:** The Endocrine Society contributed the House development of 21st Century Cures legislation. Major issues we identified included: reducing administrative burdens for researchers, expanding utilization of Central Institutional Review Boards, increasing the reproducibility of basic research, and increasing investigation of sex specific effects. We continue to work with the Senate on the Medical Innovations legislation and have advocated for incorporation of language supporting the inclusion of female subjects in pre-clinical research.

## Clinical News

### Core Quality Measures Collaborative Includes Diabetes, Obesity Measures

The Core Quality Measures Collaborative released a core set of quality measures this month that public and private payers have committed to using in their quality measurement programs as soon as possible. The Collaborative was formed with the goal of aligning measure requirements across all payers to reduce the administrative burden on providers, and also provide easily comparable information on health care quality to inform the decisions of consumers, employers, and policymakers.

The core measures are in the following seven sets. The measures were selected by the Collaborative through a review of measures in use by CMS and private payers, as well as measures endorsed by the National Quality Forum (NQF).

- Accountable Care Organizations (ACOs), Patient Centered Medical Homes (PCMH), and Primary Care
- Cardiology
- Gastroenterology
- HIV and Hepatitis C
- Medical Oncology
- Obstetrics and Gynecology
- Orthopedics

The measures included in the ACO, PCMH and Primary Care set include a number of measures on diabetes and obesity, as well as cross-cutting measures such as medication reconciliation. Preventive diabetes measures were also identified as a future area for measure development.

The Collaborative is led by the America's Health Insurance Plans and includes the Centers for Medicare and Medicaid Services (CMS), NQF, commercial plans, Medicare and Medicaid managed care plans, purchasers, physicians and other provider organizations, and consumers.

**Where We Stand:** The Society is supportive of the Collaborative's efforts and has urged CMS to align measures across payers. We will continue to provide further details as they become available as we know this will impact all of our clinical members.

## Deadlines Extended for Quality Reporting Program Data Submission

The Centers for Medicare and Medicaid Services (CMS) has extended the deadline for quality reporting data submission to March 11. Details for the PQRS and EHR programs are below. This impacts all clinical members of the Society who treat Medicare beneficiaries.

*Physician Quality Reporting System*

A complete list of 2015 PQRS data submission timeframes is below:

- EHR Direct or Data Submission Vendor (QRDA I or III) - 1/1/16 – 3/11/16
- Qualified Clinical Data Registries (QRDA III) - 1/1/16 – 3/11/16
- Group Practice Reporting Option (GPRO) Web Interface - 1/18/16 - 3/11/16

- Qualified Registries (Registry XML) - 1/1/16 - 3/31/16
- QCDRs (QCDR XML) - 1/1/16 - 3/31/16

Submission ends at 8:00 p.m. Eastern Time (ET) on the end date listed. Eligible professionals who do not satisfactorily report quality measure data to meet the 2015 PQRS requirements will be subject to a negative PQRS payment adjustment on all Medicare Part B Physician Fee Schedule (PFS) services provided in 2017. For questions, please contact the QualityNet Help Desk at 1-866-288-8912 or via email at Qnetsupport@hcqis.org. Complete information about PQRS is available on the CMS website.

*EHR Incentive Program*

Eligible professionals, eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare EHR Incentive Program can attest through the CMS Registration and Attestation System. To attest to the EHR Incentive Programs in 2015:

- Eligible Professionals may select an EHR reporting period of any continuous 90 days from January 1, 2015 through December 31, 2015
- Eligible Hospitals/CAHs may select an EHR reporting period of any continuous 90 days from October 1, 2014 through December 31, 2015

Visit the Registration and Attestation and the 2015 Program Requirements pages on the CMS EHR Incentive Programs website. For attestation questions, please contact the EHR Information Center Help Desk at (888) 734-6433.

## Research News

### NICHD Announces Third Annual Human Placenta Project Meeting

On April 14 – 15, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development will sponsor the 3rd Annual Human Placenta Project (HPP) Meeting: Understanding Human Placental Structure and Function in Real Time, Incorporating Novel Technology into the HPP. The meeting will be held at the Natcher Conference Center on the NIH main campus in Bethesda, MD.

This meeting will gather clinicians and scientists, including experts in placental biology and individuals with other subject matter expertise. The goals of the meeting are to:

- Identify scientific processes that with noninvasive monitoring will allow understanding of placental development and function
- Identify new and emerging technologies and imaging methods to achieve HPP goals
- Develop partnerships between subject matter and technology experts
- Leverage this breadth of expertise to inform the broader project roadmap and prioritize next steps

**Take Action**: We encourage interested members to register for this free meeting. For more information, please see the registration page with the agenda and other details here. The meeting will also include a poster session; the deadline to submit abstracts for the poster session is **Thursday, March 10**.

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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