Advocacy News

Senate Health Reform Proposal Vote Delayed Until After July 4; Senators' Votes in Flux – Take Action Today to Urge Your Senators to Vote No

The legislative saga of health reform continues as the US Senate struggles with coming up with 50 votes to pass its version of legislation to repeal and replace Obamacare. Following weeks of behind-closed-door negotiations by a small group of Republican Senators, Senate leaders introduced the Better Care Reconciliation Act (BCRA) of 2017 and made plans to vote on the legislation using an expedited process known as reconciliation before the July 4 holiday. Reconciliation allows the Senate to pass certain kinds of legislation with only a simple majority and not the usual requirement of 60. This meant the Republicans could pass the legislation without needing any votes from Democrats, provided they did not lose more than two members’ support. The Republicans’ plan, however, was foiled amid mounting opposition by both conservatives who believe the legislation does not go far enough and moderate Republicans who worry about the sweeping changes to the Medicaid program. The delay in the vote means that Republicans will have to negotiate among themselves to get the needed 50 votes; it also means there is more time to urge senators to vote no. All Endocrine Society members are encouraged to join our online advocacy campaign today!

The Senate legislation is similar to the House-passed legislation with a few key differences.

Like the House bill, the Senate bill would end the requirement that most Americans have health coverage while setting up a revamped system of tax credits to help people buy insurance on the individual market. It would repeal most of the taxes imposed by the Affordable Care Act, including those on high-income people and on health care companies.
The Senate bill would also make sweeping changes to Medicaid, the federal-state health program for low-income people, which would have major implications for states in the long term. The bill would roll back the expansion of Medicaid under the Affordable Care Act and it would change the broader Medicaid program from an open-ended entitlement to a program with capped payments to states.

Unlike the House bill, the Senate bill would continue the requirement banning insurers from charging people more or denying coverage based on a pre-existing medical condition, however, the Senate bill would allow states to waive other insurance rules that could weaken protections for medical conditions, such as what benefits insurers must cover and the minimum payments insurers must make toward medical bills.

The non-partisan Congressional Budget Office (CBO) released an analysis of the legislation which found that 22 million people would lose their health insurance by 2026, with 15 million losing their coverage in 2018. The legislation would save the government $321 billion over 10 years, with $772 million coming from Medicaid cuts.

**Our Position:** The Endocrine Society opposes the BCRA because it does not meet our health reform principles. We believe that people who are currently insured should not lose their coverage, there should be no lifetime caps on coverage, there should be coverage of preventive services at no cost to the patient, and there should be access to care for women’s health services. In its current form, this legislation would have a significant impact on patients with endocrine conditions.

**Take Action:** The fate of the legislation is very much in question and you can help influence the vote. We urge you to voice your concern to your Senators through our advocacy campaign. You will need to provide EITHER your home address OR your email and member ID. Our software will provide you with an email you can personalize if you choose to and will direct the email to your Senators. Taking action will only take a moment of your time, but it really can make a difference.

**Endocrine Society Joins with European Endocrine Societies to Oppose EDC Criteria; BPA Identified as a “Substance of Very High Concern”**

The European Commission has been working for several years on criteria to define endocrine-disrupting chemicals (EDCs) in the context of applicable laws. The Endocrine Society has opposed the current proposed draft under consideration by the Member States because the criteria
are excessively narrow and contain exclusions for chemicals specifically designed to disrupt certain endocrine systems in insects that have similarities to endocrine systems in wildlife and humans. Consequently, we believe the proposed criteria will fail to effectively protect the public from harms due to EDC exposures.

On June 15, the Endocrine Society prepared a letter directed to European Member State ministries that, through an outreach strategy led by Prof. Jean-Pierre Bourguignon, MD, PhD, was co-signed by Art Jan van der Lely, MD, PhD, President of the European Society of Endocrinology; Peter Clayton, MD, MRCP, FRCPCH, Secretary-General of the European Society for Pediatric Endocrinology; and Angel Nadal, PhD, Chair of the Society’s EDC Advisory Group. Representing the opinion of three of the world’s leading international medical and scientific organizations devoted to endocrine research and care, the statement opposes the proposed criteria and strenuously objects to the loopholes present in the criteria for certain pesticides. The letter urges Member States to improve the criteria by:

1. Removing the exemption for biocides and pesticides designed to act on endocrine systems;
2. Adhering to a science-based definition of EDCs that includes categories for known EDCs and chemicals for which more information is needed to make a determination; and
3. Maintaining a hazard-based identification system, without derogations based on risk.

The next meeting for Member State representatives to discuss and potentially vote on the criteria will be on July 4th. Following a vote for approval, the criteria would go to the European Parliament for a vote. However, the new French government has emerged as a key player in the debate on the EDC criteria. Recently, France reaffirmed that they do not support the current proposal, and that it seeks a greater level of public health protection. Environment Minister Nicolas Hulot indicated that France is negotiating directly with Germany to improve the criteria, suggesting that the criteria are still open to modifications that could be supported by the Endocrine Society. Encouragingly, a proposal led by France to identify bisphenol A (BPA) as a substance of very high concern (SVHC) recently passed the Member State Committee. The identification of BPA as an SVHC was based on its ability to cause human health impacts due to endocrine-disrupting properties.

The Endocrine Society will continue to keep members informed of this rapidly-developing issue and advocate for criteria that will protect the public from EDC-associated health risks.
Clinical News

Policymakers Continue to Debate Drug Pricing; White House Releases Draft Executive Order

The White House has released a draft Executive Order (EO) outlining federal policies to reduce the cost of medical products and to enhance biomedical innovation. The EO outlines the importance of accelerating the marketing of new and innovative therapies, reducing burdens from regulatory or administrative actions that inflate or distort prices, facilitating value-based reimbursement arrangements in federal health programs, and evaluating other methods to lower drug costs. The EO also directs the Secretary of Health and Human Services to work with the FDA to advance innovation and encourage lower-cost alternatives and to take steps through the Centers for Medicare & Medicaid Services to develop new care models that leverage new approaches to benefit design to reduce out of pocket spending. Finally, the EO would also restrict funds from the 340B discount program to low-income and otherwise vulnerable populations. While addressing rising drug costs is critical, the EO does not make significant changes to federal policies such as negotiating drug pricing or allowing lower cost drugs to be imported.

The Society has called for full transparency across the supply chain as a key first step in understanding rising drug costs and will continue to monitor this issue as the President considers whether to sign the EO in its current form. Drug manufacturers have been working to address this issue through evaluating new benefit design models and by bolstering patient assistance programs.

Additional Resources:

- Eli Lilly & Co. unveiled a new website to help patients who have high-deductible plans or no insurance access to insulin.
- The Washington Post published an opinion piece by Endocrine Society member David M. Tridgell on what needs to be done to control insulin prices.

FDA Votes in Favor of Victoza

On July 21, the FDA Endocrinologic and Metabolic Drugs Advisory Committee held a hearing to review cardiovascular outcomes data from the LEADER trial for Victoza (liraglutide). The advisory committee voted 17-2 in favor of Victoza on whether there was substantial evidence that
Victoza reduces cardiovascular risk in patients with type 2 diabetes. The Endocrine Society submitted testimony in support of therapies like Victoza that reduce cardiovascular disease in people with diabetes and called on the FDA to expedite review of emerging therapies that reduce complications and impact the progression of the disease. The FDA will now consider the advisory committee’s recommendation for including this data in the drug label.

**Congress Considers FDA User Fee Reauthorizations**

The FDA’s medical product user fee legislation authorizes the agency to collect user fees from drug and device manufacturers. The first of these user fee laws was the Prescription Drug User Fee Act (PDUFA), passed in 1992. The statutory provisions expire and must be reauthorized every five years so that the agency can continue collecting these fees that help support the agency’s operations. This year, medical devices (MDUFA), generic drugs (GDUFA), and biosimilars (BsUFA) must all be reauthorized as well as PDUFA. If user fees are not reauthorized, FDA staff, including those that review marketing applications, harming the FDA’s ability to review pending applications and approve new medical products, could face layoffs.

On May 11, the Senate Committee on Health, Education, Labor and Pensions (HELP) marked up the UFA reauthorization bill S.934 and voted to pass it on to the full chamber by a 21-2 vote. On that same day, the bill was placed on the Senate’s legislative calendar. The bill reauthorizes the user fees paid by drug and device sponsors and does not include the user fee hikes proposed in President Trump’s budget. It also instructs the FDA to examine the barriers to clinical trial participation and blocks the importation of drugs that are “not safe for use except under the supervision of a practitioner licensed by law to administer such a drug” or are subject to Risk Evaluation and Mitigation Strategy (REMS) proposals. In the House of Representatives, H.R. 2430 was introduced on May 16 and was unanimously approved during the House Energy and Commerce Committee’s mark up on June 7 by a vote of 54-0. The FDA’s authorization to collect medical product user fees expires on September 30, requiring that the new law be in place by October 1. Both chambers are expected to take up the legislation in July.

**QPP Year 2 Propose Rule Released**

The Centers for Medicare and Medicaid released its proposal for the second year of the Quality Payment Program (QPP). 2017 is a transition year for the QPP, allowing clinicians to "pick their
pace" at which they choose to participate. The proposed rule carries over many of the requirements from the 2017 reporting year, and makes changes that aim to reduce the reporting burden and allow clinicians to spend more time with their patients. Highlights of the proposed structure for 2018 Merit-based Payment System (MIPS) include:

- Increases the low-volume threshold for those clinicians who are exempt from the program to less than or equal to $90,000 in Medicare Part B charges OR less than or equal to 200 Part B beneficiaries (less than or equal to $30,000 in charges or less than or equal to 100 Part B beneficiaries in 2017).

- Allow individual clinicians or small practices to form Virtual Groups for reporting purposes.

- Continue to allow use of 2014 edition Certified Electronic Health Record Technology (CEHRT) and provide bonus points to those that use only 2015 edition CEHRT.

- Provide bonus points for the management of complex patients.

- Reward improvement in the Quality performance category based on changes in quality of care from the previous year. Scoring will be based on rate of improvement so that higher improvement results in more points, particularly those improving from lower performance in the transition year.

- Performance categories will be weighted the same as 2017 (60% Quality, 25% Advancing Care Information, 15% Improvement Activities, 0% Cost).

- The performance period for Quality will be the full calendar year, and 90-day performance period for Advancing Care Information and Improvement Activities.

We will review the rule in more depth and provide comments to CMS on issues that impact endocrinologists.

Society Launches Redesigned QPP Website; New QPP Program Resources Available from CMS

The Society has redesigned its Quality Payment Program (QPP) resource page to better serve our members who will be eligible for participation in the QPP. The site provides an overview of program requirements and provides resources to give the user more in-depth information from
the Society, the Centers for Medicare and Medicaid Services (CMS), the American Medical Association, and the American College of Physicians.

CMS has released new resources to help clinicians successfully participate in the first year of the QPP. The MIPS Quick Start Guide, fact sheet on the Medicare Shared Savings Program and QPP, and a MIPS Advanced Practice Model fact sheet are available on the Society's QPP resource page and the CMS QPP website.

We are committed to providing our members with valuable information to support them in the transition to the new payment system. If there are specific resources that you would like to see offered by the Society, please contact Stephanie Kutler, Director, Advocacy & Policy at skutler@endocrine.org.

Research News

NIH Rolls Back Proposal to Limit Grant Support to Individual Investigators

In May, the National Institutes of Health (NIH) proposed to implement a new policy to place a cap on total research support that may be received by an individual investigator. The cap, based on a metric called the Grant Support Index (GSI), would be equivalent to 3 R01-series grants. As of June 12, the Endocrine Society has learned that the NIH is no longer proposing any cap on grants, but will instead pursue an entirely new policy to accomplish the goal of balancing funding support across all career stages.

The new policy, called the Next Generation Researchers Initiative, will allocate an estimated $210 million per year, increasing by ~$210 million each year, to arrive at a total of ~$1.1 billion per year, to raise the payline for early stage investigators (ESIs) who have been principal investigators (PIs) for less than or equal to 10 years and are in danger of losing NIH support. The policy will extend to those PIs seeking their second NIH grant. Funding for this initiative will come from reprioritization of NIH funds and use of innovative grant mechanisms such as the R56 and R35 programs. Over a longer timeframe, NIH will also develop metrics of productivity to better enhance stewardship of taxpayer dollars and assess research output by measuring various outcomes such as patents, medical interventions, changes to medical practice.

The Endocrine Society is encouraged that the NIH took into account feedback received from various sources to revise their approach to supporting researchers throughout their careers. We appreciate that NIH will continue to use stakeholder input to inform short and long-term actions.
in pursuit of this goal. For more information, please see the presentation “Enhancing Stewardship: The Next Generation of Researchers Initiative” on the NIH website at https://acd.od.nih.gov/.

NIGMS Seeks Input on Physician-Scientist Training

On June 9, the National Institute of General Medical Sciences (NIGMS) issued a Request for Information (RFI) on “Strategies to Enhance Physician-Scientist Training through the NIGMS Medical Scientist (M.D.-Ph.D.) Training Program (MSTP).” The NIGMS is unique among the Institutes and Centers at the NIH for its focus on training, and through this RFI they seek new strategies and ideas to modernize physician-scientist training. The scope of specific input requested includes the following areas:

- Trainees
- Financing/Funding
- Dual-Degree Training
- NIGMS Management of MSTP Grants

Take Action: The Endocrine Society recognizes that physician-scientists face unique challenges throughout their training, and we have advocated for expanded interdisciplinary training and mentorship opportunities for physician-scientists. We encourage members of the Endocrine Society to respond to the RFI in advance of the August 9 deadline via the NIH web form. For more information, please see the full NIH notice.

NIH Announces sIRB Administrative Supplements, Revises Effective Date for Policy on sIRBs

On June 16, the National Institutes of Health (NIH) issued a notice encouraging Clinical and Translational Science Award (CTSA) recipients to apply for administrative supplements to “develop resources needed to facilitate single Institutional Review Board (SIRB) review for multisite research.” The supplements will cover up to $300,000 in direct costs for one year. Additional priority will be given to institutions that will propose to collaborate with other organizations outside their networks. For more information, please see the NIH notice here.
At the same time, the NIH also issued a separate notice to inform the research community that the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research would now have an effective date of January 25, 2018. For more guidance on the policy, please see the NIH website.

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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