April 14, 2016

Advocacy News

Society Celebrates World Health Day—Raises Awareness about Diabetes

April 7th marked World Health Day, a global campaign conducted each year to highlight the most pressing public health issues. This year the campaign focused on beating diabetes given the more than 400 million people worldwide who have been diagnosed with this disease, a number which is expected to more than double over the next two decades.

To raise awareness about this important issue, the Society disseminated two advocacy campaigns to our U.S. Members. One campaign asked members of Congress to support Medicare coverage of continuous glucose monitors, and the other called for increased funding for the National Institutes for Health. International members were also encouraged to support the message of World Health Day by engaging in social media activities. We also participated in an event at the White House to discuss ways to improve care for patients with diabetes in the United States.

Take Action: If you were unable to participate in the Society's advocacy campaigns on World Health Day, it's not too late. Join our campaigns to urge Congress to increase NIH funding and/or to support Medicare coverage of CGM. Our advocacy software will provide a letter and direct your email to your Representative and Senators. All you need to do is provide your zip code; no Member ID is needed.

NIH Director Testifies for FY 2017 Funding; Highlights Endocrine Society Priorities

On Thursday, April 7th the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee conducted a hearing to review the Fiscal Year (FY) 2017 budget

request and funding justification for the National Institutes of Health (NIH). During the hearing, NIH Director Francis Collins, MD, joined several Institute Directors to take questions from legislators and discuss NIH priorities, and took the opportunity to highlight Endocrine Society funding priorities.

During his testimony, Dr. Collins discussed 10 areas where he anticipates major progress in the next 10 years, if the NIH receives adequate funding. One of his predictions was the "introduction of a safe and effective artificial pancreas" for patients with diabetes, a top priority of the Society. He also mentioned that he sees significant promise for research on diabetes, generally. Senator Jeanne Shaheen (D-NH) was particularly enthusiastic about the potential to improve care for patients with diabetes and asked Dr. Collins how he could accelerate the timeframe for progress in this area. Dr. Collins maintained that the NIH needs steady and sustainable funding trajectories to support research. Specifically, he suggested that yearly increases of 5% would be a sustainable trajectory for NIH.

Representatives from the NIH also discussed two additional Endocrine Society priorities: 1) The importance of funding the next generation of biomedical researchers, and 2) The need to support basic research. Dr. Collins described methods that the Institute uses to support early career investigators by giving them preferential treatment during grant review. Several of the NIH representatives, including Dr. Collins, spoke in support of basic research as fundamentally important for downstream advances that result in new cures and therapies. Walter Koroshetz, MD, the Director of the National Institute of Neurological Disorders and Stroke stressed that the unpredictable nature of basic research was necessary to explore new opportunities and frontiers. Subcommittee Chairman Roy Blunt (R-MO) agreed, stating that you "can't prescribe results."

The Subcommittee then debated the prospect of replacing appropriated funds with mandatory funds, as proposed in the President's budget. Dr. Collins shared his concern about the prospect of a cut to the NIH appropriation, suggesting that a $1B cut would result in substantial reductions to new and competing grants, damaging the momentum gained from the increase to the NIH budget in FY 2016. He indicated that mandatory funds might be used for certain projects with discrete timeframes; however, mandatory funds would not be an adequate replacement for discretionary funds typically to support NIH. Senator Barbara Mikulski (D-MD) also expressed her objection to the use of mandatory funds to support NIH, given that such funds require the identification of new revenue sources.

The Endocrine Society is encouraged that the Director's comments reflected the advocacy priorities of Society members and that Senators asked questions recommended by the Society. We

have long supported the adoption of artificial pancreas technology through our advocacy program, and we are glad that Dr. Collins recognizes the potential of this groundbreaking technology on the lives of patients. The Endocrine Society also advocates for steady increases in funding that would allow the NIH grant success rate to return to a more sustainable level. We will continue to advocate for increased federal funding for research; on Friday the Society will submit testimony in support of NIH funding, highlighting the critical advances made by NIH-funded endocrine scientists over the past 100 years.

Take Action: It is critical that all Members of Congress hear from their constituents about the value of NIH and the need to prioritize and support funding for the NIH. Please join our online campaign to contact your Senators and Representative. The campaign provides a letter which will be directed to your congressional delegation. You only need to provide your zip code; no Member ID is needed.

Senate Considers Final Group of Medical Innovations Bills; Includes Society Recommendations on Reducing Burdens to Researchers and Gender Inclusion

As mentioned previously in *Endocrine Insider*, The Senate Health, Education, Labor and Pensions (HELP) Committee has begun consideration of 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 about electronic health systems.

On Wednesday, April 6, the Senate HELP Committee met in executive session to discuss the final package of legislation for the Medical Innovations initiative, which included:

- S.2700, FDA and NIH Workforce Authorities Modernization Act
- S.185, Promise for Antibiotics and Therapeutics for Health Act
- S.2713, Advancing Precision Medicine Act of 2016
- S.2745, Advancing NIH Strategic Planning and Representation in Medical Research Act
- S.2742, Promoting Biomedical Research and Public Health for Patients Act

The Medical Innovations package includes several issues the Society advocated for. For example, the FDA and NIH Workforce Authorities Modernization Act contains language that would exempt scientific meetings attended by scientific or medical personnel from onerous travel restrictions imposed on federally funded scientists and clinicians. Additionally, the Advancing NIH Strategic Planning and Representation in Medical Research Act would direct the NIH to develop policies for basic research projects to include and analyze sex as a biological variable where appropriate. Importantly, the bill instructs NIH to conduct outreach to solicit feedback on when it is appropriate for basic research projects to include both sexes. These are big advocacy victories for us. Over the past year, the Endocrine Society worked with Senate offices on: 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 appreciate all of the work of Society members in sharing these issues with Members of Congress, and we will continue to work with the House and Senate on passage of the legislation.

Outlook: Although the House has passed the 21st Century Cures bill, the fate of the Senate Medical Innovations legislation is unclear. 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, and Chairman Alexander indicated that the Medical Innovations package would not go to the Senate for a vote until the funding issues were resolved. Even if the Senate passes the legislation, differences between the House and Senate bills would need to be worked out in a conference agreement and passed by both chambers. We will keep you apprised of developments.

Clinical News

FDA Issues Label Changes for Diabetes Drugs

The U.S. Food and Drug Administration (FDA) has issued label changes for both metformin-containing medicines for diabetes and for those containing saxagliptin and alogliptin. The FDA has stated that medicines containing metformin will undergo label changes for patients with reduced kidney function which would expand its use in these patients. The current labeling strongly recommends against use of metformin in some patients whose kidneys do not work normally because of the increased risk for lactic acidosis. However, following a review of numerous medical studies on the safety of metformin use in patients with mild to moderate impairment in kidney function, the FDA concluded that metformin can be used safely in patients

with mild kidney function impairment and in some patients with moderate kidney function impairment. Due to these findings, the FDA will be issuing a label change for medicines containing metformin to reflect this new information.

Health care professionals should follow the latest recommendations when prescribing metformin-containing medicines to patients with impaired kidney function. The FDA is also recommending that the measure of kidney function used to determine whether a patient can receive metformin be changed from one based on a single laboratory parameter (blood creatinine concentration) to one that provides a better estimate of kidney function in patients with kidney disease (i.e., glomerular filtration rate estimating equation (eGFR)).

The FDA has also issued a safety alert for medicines containing saxagliptin and alogliptin due to an increased risk of heart failure—particularly in patients who already have heart or kidney disease. The FDA has issued new warnings to these drug labels, including:

- Onglyza (saxagliptin)
- Kombiglyze XR (saxagliptin and metformin extended release)
- Nesina (alogliptin)
- Kazano (alogliptin and metformin)
- Oseni (alogliptin and pioglitazone)

The FDA recommends that health care professionals consider discontinuing medications containing saxagliptin and alogliptin in patients who develop heart failure and monitor their diabetes control. This guidance further states that if a patient's blood sugar level is not well-controlled with their current treatment, other diabetes medicines may be required.

To report adverse events or side effects related to the use of these products, please contact the FDA's MedWatch Safety Information and Adverse Event Reporting Program or call 1-800-332-1088 to request a reporting form.

Dexcom Issues Recall for G4 Platinum and G5 Mobile Continuous Glucose Monitoring System Receivers

Dexcom has issued a recall for G4 Platinum and G5 Mobile Continuous Glucose Monitoring (CGM) system receivers due to audible alarm failures when hypoglycemia or hyperglycemia are detected. All models and lots manufactured between July 29, 2011 and March 10, 2016 are affected by the recall. Dexcom notified patients using these devices on February 23, 2016 and issued the following instructions to test the audio alert on the receiver:

- press the center button on your receiver to access the Main Menu
- scroll down to Profiles
- select Profiles
- scroll down to Try It
- select Try It
- scroll down to 55 Fixed Low
- select 55 Fixed Low
- verify that you receive vibrations first (vibratory portion of alarm), followed by beeps (audible portion of alarm).

Patients should contact Dexcom at (844) 607-8398 if the audio alert does not work properly. Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

Open Payments Review and Dispute Period Now Open

Eligible providers and teaching hospitals can review their 2015 Open Payments Data through May 15, 2016, and dispute any erroneous data. After the conclusion of the review and dispute period, CMS will publish the 2015 payment data and updates to the 2013 and 2014 data on June 30, 2016.

The Open Payments database publicly reports transfers of value made to physicians and teaching hospitals by pharmaceutical companies and device manufacturers. Although review of data

contained in the database is optional, providers are encouraged to verify the data submitted by industry during the review and dispute period. Providers should email Medicare's Open Payment Help Desk at openpayments@cms.hhs.gov, or call (855) 326-8366 with any questions on the Open Payments process.

Comprehensive Primary Care Plus Pilot Project Announced by CMMI

Building on the success of previous pilot projects, the Centers for Medicare and Medicaid Services Center for Medicare and Medicaid Innovations (CMMI) announced an advanced primary care model aimed at strengthening primary care services. The Comprehensive Primary Care Plus (CPC+) pilot project will begin in January 2017 and will be tested over a five-year period. CPC+ is a regionally-based, multi-payer care delivery and alternative payment model (APM) that aims to reward value and quality through a new payment structure. It is anticipated that the pilot project will be tested in up to 20 regions across the country and cover 25 million patients. The model will offer two tracks with incrementally advanced care delivery requirements and payment options.

Although this model will not directly impact endocrinologists, we are watching the development closely for indications of CMS' priorities for APMs. There is currently no APM that is endocrine-specific, and we are considering potential opportunities for a new payment model.

More information on the model can be found on the Comprehensive Primary Care Plus web page.

Research News

NIGMS Seeks Biomedical Research Community Input on Support for Research Resources

On April 4, the National Institute of General Medical Sciences (NIGMS) issued a request for information (RFI) on the "Need for and Support of Research Resources for the Biomedical Research Community." NIGMS is interested in the development of biomedical technologies, and ensuring that these technologies are made available to investigators as resources.

NIGMS seeks input on how existing research resources are supported and whether and how federal support should be provided. NIGMS is also interested in the review of grant applications

to fund resources, and how resources might be evaluated to determine impact and effectively allocate funds.

Take Action: We encourage members to examine the specific information requested by NIGMS, and consider responding to the RFI, by reviewing the link here: NIGMS RFI. Please note that responses must be submitted by June 3, 2016.

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