# Sleep Research Society Washington Update June 6, 2017

The November 2016 election brought a great deal of change and uncertainty to Washington. Republicans maintained control of the House and Senate moving into the 115<sup>th</sup> Congress, but also captured the White House. With single party control of the legislative agenda, Republican leadership sought to move quickly to advance a key campaign promise, to "repeal and replace" the *Patient Protection and Affordable Care Act* (ACA/Obamacare). However, the task of overhauling the U.S. healthcare system has proven divisive and complicated, and six-months into the year conservative ACA reform efforts are barely maintaining momentum and only slowly moving forward.

Despite the hyper-partisanship currently gripping Capitol Hill, lawmakers managed to pass an FY 2017 omnibus appropriations package that included all pending spending measures. While the enactment of FY2017 appropriations took place well into the fiscal year, research and patient care advocates were pleased to see that the final measure included meaningful funding increases for many health service agencies and programs. Most notably, Congress made good on the promise to provide additional resources when the 21<sup>st</sup> Century Cures Act was passed and included roughly \$2 billion in increased funding for the National Institutes of Health.

The community's enthusiasm for new and sustained investments in medical research and patient care was short-lived. Not long after the FY 2017 omnibus package was enacted, the Trump Administration released their non-binding FY 2018 budget request. The proposal recommends deep cuts to the National Institutes of Health, the elimination of the Agency for Healthcare Research and Quality, and additional cuts to healthcare programs at the Department of Defense and the Veterans Administration. Fortunately, the budget request was met with strong condemnation by high-profile lawmakers from both sides of the political aisle.

The SRS continues to actively advocate for community priorities through ongoing congressional outreach and education. Our approach has seen success over recent years as funding and policy recommendations are directed to support federal sleep, sleep disorders, and circadian activities. The current headwinds facing our community though call for a doubling-down on advocacy and outreach efforts, including educating new lawmakers about the value and importance of sleep research, and cultivating additional congressional champions. Only through strong congressional support and administration collaboration can we ensure continued investment in the field.

Below, please find a summary of key advocacy items.

## FY 2017 Appropriations

## **FY 2017 Omnibus Appropriations Package**

- \$7.26 billion for the Centers for Disease Control and Prevention (CDC), an increase of \$21.76 million over FY 2016.
  - \$1.12 billion for Chronic Disease Prevention and Health Promotion at CDC (\$777.65 million in discretionary funding and \$337.95 million from the Prevention and Public Health Fund), a decrease of \$61.5 million from FY 2016.
- \$34.1 billion for the National Institutes of Health (NIH), an increase of \$2 billion over FY 2016.
  - \$5.39 billion for the National Cancer Institute at NIH, an increase of \$174.63 million over FY 2016.
  - \$3.21 billion for the National Heart, Lung, and Blood Institute at NIH, an increase of \$91.01 million over FY 2016.
  - \$1.78 billion for the National Institute of Neurological Disorders and Stroke at NIH, an increase of \$87.52 million over FY 2016.
  - \$2.05 billion for the National Institute on Aging at NIH, an increase of \$448.42 million over FY 2016.
  - \$1.60 billion for the National Institue of Mental Health at NIH, an increase of \$53.54 million over FY 2016.
  - \$2.65 billion for the National Institute of General Medical Sciences, an increase of \$138.77 million over FY 2016.
  - \$1.38 billion for the National Institute of Child Health and Human Development at NIH, an increase of \$40.49 million over FY 2016.
  - \$1.66 billion for the Office of the Director at NIH, an increase of \$106.58 million over FY 2016.
    - This funding level includes \$682.86 million for the Common Fund at NIH, an increase of \$19.81 million over FY 2016.
- \$300 million for the Department of Defense Peer-Reviewed Medical Research Program (PRMRP), an increase of \$22 million over FY 2016 (eligible conditions list below).
  - Consistent with previous funding cycles, "sleep disorders" is once again listed as a condition eligible for study through the PRMRP.

- The PRMRP funding opportunities for FY 2017 where recently released and they can be viewed here:
  - DOD

Department of Defense
Dept. of the Army -- USAMRAA
DoD Peer Reviewed Medical Discovery Award
Synopsis 1

http://www.grants.gov/web/grants/view-opportunity.html?oppId=294159

DOD

Department of Defense
Dept. of the Army -- USAMRAA
DoD Peer Reviewed Medical Focused Program Award
Synopsis 1
http://www.grants.gov/web/grants/view-opportunity.html?oppId=294160

DOD

Department of Defense
Dept. of the Army -- USAMRAA
DoD Peer Reviewed Medical Investigator-Initiated Research Award
Synopsis 1
<a href="http://www.grants.gov/web/grants/view-opportunity.html?oppId=294161">http://www.grants.gov/web/grants/view-opportunity.html?oppId=294161</a>

DOD

Department of Defense
Dept. of the Army -- USAMRAA
DoD Peer Reviewed Medical Technology/Therapeutic Development Award
Synopsis 1
http://www.grants.gov/web/grants/view-opportunity.html?oppId=294162

• \$675.37 million for the VA Medical and Prosthetic Research Program, an increase of \$44.63 million over FY 2016 (the FY 2017 Military Construction and Veterans Affairs Appropriations Bill was the only spending bill passed ahead of the omnibus package).

#### FY 2017 House L-HHS Bill, Key Committee Recommendations

Young Investigators.—The Committee expects NIH to report on actions it has taken to lower the median age at which investigators receive their first R01 awards annually in the fiscal year 2018 budget request and future budget requests. In addition, the NIH shall submit an accompanying plan outlining concrete steps to lower the median age at which individuals receive their first R01 award within 180 days of enactment. The Committee further expects NIH to convene a working group consisting of stakeholders from academia, young researchers, industry leaders, and government officials to move forward on this goal.

## FY 2017 Senate L-HHS Bill, Key Committee Recommendations

Sleep Surveillance.—The Committee is pleased by CDC's work on a national public health awareness campaign for sleep. The Committee urges CDC to ensure that funding for surveillance activities on sleep disorders and sleep health is maintained in addition to these awareness efforts.

Sleep Phenotypes.—The health consequences of sleep disorders such as obstructive sleep apnea and insomnia include increased risk of hypertension, cardiovascular disease and obesity. The Committee is encouraged by NHLBI's efforts to improve our understanding of sleep disorders and urges NHLBI to partner with other NIH Institutes to continue advancing research for sleep phenotypes and biomarkers that further explore health disparities and the intersection between chronic diseases and sleep.

#### FY 2018 Budget Request

# **Proposed Funding Levels**

- \$5.975 billion for CDC program level, a cut of \$1.2 billion below FY 2017.
  - \$952 million for Chronic Disease Prevention and Health Promotion at CDC, a proposed decrease of \$168 million from FY 2017, including \$500 million from the Prevention and Public Health Fund (an increase of \$112 million over in PPHF funding FY 2017).
    - Line item (often disease-specific) CDC programs are eliminated and replaced with a new \$500 million "America's Health Block Grant Program" for states and tribal organizations [please see language below].
- \$26.9 billion for NIH program level, a cut of \$7.2 billion below FY 2017. The budget proposal recommends cuts for each NIH institute and center, and recommends capping NIH payments of indirect costs.
  - \$4.47 billion for the National Cancer Institute at NIH, a proposed decrease of \$920 million from FY 2017.
  - o \$2.54 billion for the National Heart, Lung, and Blood Institute at NIH, a proposed decrease of \$670 million from FY 2017.
  - o \$1.36 billion for the National Institute of Neurological Disorders and Stroke at NIH, a proposed decrease of \$420 million from FY 2017.
  - \$2.19 billion for the National Institute of General Medical Sciences at NIH, a proposed decrease of \$460 million from FY 2017.

- \$1.3 billion for the National Institute on Aging at NIH, a proposed decrease of \$705 million from FY 2017.
- \$215 million for the National Institute on Minority Health and Health Disparities at NIH, a proposed decrease of \$74.1 million from FY 2017.
- o \$557 million for the National Institute for Advancing Translational Sciences at NIH, a proposed decrease of \$148.9 million from FY 2017.
- \$1.45 billion for the Office of the Director at NIH, a proposed decrease of \$21 million from FY 2017.
- \$0 for the Agency for Healthcare Research and Quality, a cut of \$324 million. The budget proposal recommends consolidating the functions of AHRQ into NIH.
- \$640 million for the VA Medical and Prosthetic Research Program, a proposed decrease of \$35 million from FY 2017.
- \$34.6 billion for the Defense Health Program, a proposed decrease of \$560 million from FY 2017.
  - Congressionally directed medical research programs at the Department of Defense, including the Peer-Reviewed Medical Research Program, are traditionally not included in the administration's budget request.
- Roughly \$880 million in cuts to Medicaid and \$72.5 billion in cuts to Social Security Disability Insurance (over the next 10 years), which would effectively cut the programs in half in terms of resources available.

[administration responses to recent congressional committee recommendations can be viewed on next page]

# Sleep Health and Cancer

The Committee understands the complex intersection between sleep health and cancer development, cancer progression, and remission. The Committee encourages NCI to explore the role of sleep in cancer development and progression.

#### Action taken or to be taken

The National Cancer Institute (NCI) recognizes the vital role sleep plays in overall health and well-being in cancer patients and survivors. Recent studies have revealed that chronic lack of sleep may lead to higher risk of prostate, <sup>191</sup> breast, <sup>192</sup> and colorectal <sup>193</sup> cancer. In people living with cancer, physical illness, pain, hospitalization, and drugs and other treatments, as well as the psychological impact of malignant disease, may disrupt sleeping patterns. <sup>194</sup> Anxiety and depression – common psychological responses to the diagnosis of cancer, cancer treatment, and hospitalization – are highly correlated with insomnia.

At NCI designated cancer centers like the University of Pittsburgh Cancer Institute and the MD Anderson Cancer Center, sleep clinics help cancer patients, who are three times more likely to have trouble sleeping that those who do not have cancer, improve their sleep. Clinics address sleep problems by using behavioral treatments, which may be more effective and cause fewer side effects with longer-lasting benefits than taking medication alone.

In addition, NCI supports a broad portfolio of cancer research and sleep health as noted in the observational and interventional study examples below:

- A prospective study of the impact of breast cancer on the relationships between inflammation and symptoms of fatigue, depression, sleep, and cognition that compares breast cancer survivors and age-matched controls.
- A study of breast cancer survivors that examines the relationships between sleep disturbances, cellular and genomic markers of inflammation, and depression occurrence.
- A proposed phase II trial that examines the impact of Brief Behavioral Therapy (BBT) on insomnia, mood, and quality of life, as well as circadian rhythm disruption, autonomic dysfunction, and sleep-wake cycles, in a clinical oncology community clinic.
- A phase III trial exploring the use of a BBT for patients with insomnia who are receiving chemotherapy for breast cancer.
- A phase I study that uses cognitive-behavioral treatment (CBT) to target the specific needs of cancer survivors with insomnia to significantly improve quality of life. Phase II and phase III of the study will include a randomized controlled trial of 50 cancer survivors to compare the efficacy of the CBT intervention.
- A phase III trial study on yoga or stretching and relaxation in improving physical function in patients with stage 0-III breast cancer undergoing radiation therapy.
- A phase III randomized controlled trial comparing yoga to cognitive behavioral therapy and a health education control on insomnia in cancer survivors 6-12 months following adjuvant treatment.

NCI will continue to support promising research opportunities that reveal the connection between sleep health and cancer development, progression, and remission in order to help cancer patients and survivors live healthier lives.

# Sleep Phenotypes

The health consequences of sleep disorders such as obstructive sleep apnea and insomnia include increased risk of hypertension, cardiovascular disease, and obesity. The Committee is encouraged by NHLBI's efforts to improve our understanding of sleep disorders and urges NHLBI to partner with other NIH Institutes to continue advancing research for sleep phenotypes and biomarkers that further explore health disparities and the intersection between chronic diseases and sleep.

# Action taken or to be taken

The National Center on Sleep Disorders Research (NCSDR), located within the National Heart, Lung, and Blood Institute (NHLBI), continues to support research on how differences in sleep health contribute to racial, ethnic, gender, and socioeconomic disparities in cardiovascular health. In 2016, NCSDR published the recommendations of an NHLBI workshop entitled "Reducing health disparities: the role of sleep deficiency and sleep disorders." Ongoing NHLBI-supported studies are investigating the importance of sleep to disparities in cardiovascular disease risk in African Americans, Hispanics, and other diverse populations. A joint initiative between NHLBI and the *Eunice Kennedy Shriver* National Institute on Child Health and Human Development (NICHD) has identified sleep health risks that are specific to pregnant women. These studies indicate that untreated sleep apnea and sleep deficiency increase the risk of gestational hypertension and diabetes by three- to five-fold. A follow-up study is underway to determine whether sleep problems during pregnancy increase the future maternal risk of cardiovascular disease. A new NHLBI-NICHD partnership is planned for Fiscal Year 2017 to determine whether treating sleep apnea during pregnancy can reduce cardiometabolic risks to pregnant women (such as gestational diabetes and high blood pressure).

The NHLBI also leads efforts to stimulate the development of sleep biomarkers. A workshop funded by NHLBI and the National Institute on Aging, held in partnership with the Sleep Research Society, examined the need for biomarkers of chronic sleep loss, sleep apnea screening, and circadian phase. A resulting study was funded to identify specific changes in metabolism that consistently occur during insufficient sleep. Further, the NHLBI's Trans-Omics for Precision Medicine (TOPMed) program supports gene sequencing and state-of-the art molecular analyses in cohorts where sleep health has been studied.

Recent advances suggest a need to identify biomarkers for sleep disturbances related to artificial light exposure. With NCSDR input, the National Toxicology Program of the National Institute of Environmental Health Sciences (NIEHS) has completed an evidence-based review of health risks associated with artificial light at night; a report summarizing the findings is in preparation. In August 2016, an NHLBI Workshop on Light and Circadian Health evaluated preliminary findings from the review, and concluded that light, circadian rhythm, and sleep are essential physiological requirements for optimal human development, health, and wellness across the lifespan. In 2017, NHLBI is sponsoring the first nationally representative survey of sleep schedules and health risks among U.S. adults, and will work with the Sleep Disorders Research Advisory Board and scientific program staff across NIH to update the NIH Sleep Disorders Research Plan.

## **Advocacy Activities**

#### **Recent Agency Meetings**

- National Institute of Neurological Disorders and Stroke, Dr. Walter Koroshetz
- National Institute of General Medical Sciences, Dr. Judith Greenberg
- National Heart, Lung, and Blood Institute, Dr. Gary Gibbons
- National Institute on Aging, Dr. Mary Bernard
- National Institute of Mental Health, Dr. Dr. Aleksandra Vicentic
- National Cancer Institute, Dr. Ann O'Mara
- VA/Million Vets Project, Dr. Jennifer Mauser
- Patient Centered Outcomes Research Institute, Joe Selby
- National Highway Traffic Safety Administration, Dr. Mark Rosekind
- NIH Precision Medicine Initiative, Dr. Stephanie Devaney
- NIH Office of Behavioral and Social Sciences Research, Dr. William Riley

#### **Recent Congressional Meetings**

- Congressman Bill Foster (D-IL): Represents SRS
- Congressman Albio Sires (D-NJ): Member, Transportation Committee
- Congressman Sam Graves (R-GA): Member, Transportation Committee
- Senator Richard Durbin (D-IL): Member, Appropriations Committee
- Senator Elizabeth Warren (D-MA): Member, HELP Committee
- Senator Bob Casey (D-PA): Member, HELP Committee
- Senator Chris Van Hollen (D-MS): Member, Appropriations Committee

### **Grassroots Congressional Outreach**

- Congresswoman Susan Davis (D-CA)
- Congressman Scott Peters (D-CA)
- Senator Diane Feinstein (D-CA), Member Appropriations Committee
- Congressman Jim McGovern (D-MA)
- Senator Elizabeth Warren (D-MA): Member, HELP Committee
- Congressman Mark Pocan (D-WI), Member Appropriations Committee
- Senator Tammy Baldwin (D-WI), Member, HELP Committee
- Congressman Brad Wenstrup (R-OH)
- Congressman Mike Doyle (D-PA): Member, Energy & Commerce Committee
- Senator Bob Casey (D-PA)
- Congresswoman Jackie Walorski (R-IN)
- Senator Joe Donnelly (D-IN)

# **Additional activity**

For the 115<sup>th</sup> Congress, SRS sent a welcome letter to all Representatives and Senators explaining the organizations priorities, advanced report language recommendations prioritizing research and funding recommendations for FY 2018 and FY 2017, submitted House and Senate appropriations testimony, and continued to collaborate with the Department of Transportation on the Drowsy Driving Compendium and securing congressional support.

#### LEGISLATIVE AGENDA

The Sleep Research Society (SRS) was established in 1961 by a group of scientists who shared a common goal to foster scientific investigations on all aspects of sleep and sleep disorders. Since that time, SRS has grown into a professional society comprising over 1,300 researchers nationwide. From promising trainees to accomplished senior level investigators, sleep research has expanded into areas such as psychology, neuroanatomy, pharmacology, cardiology, immunology, metabolism, genomics, and healthy living. SRS recognizes the importance of educating the public about the connection between sleep and health outcomes. SRS promotes training and education in sleep research, public awareness, and evidence-based policy, in addition to hosting forums for the exchange of scientific knowledge pertaining to sleep and circadian rhythms.

#### SLEEP & SLEEP DISORDERS RESEARCH IS IMPORTANT

- 50-70 million Americans across all demographic groups chronically suffer from a sleep disorder; however, studies show that minority populations suffer at a disproportionate rate.
- Adults who do not get enough sleep on a regular basis are more likely to suffer from chronic conditions, including obesity, hypertension, diabetes, poor mental health, and injuries. Adults 18-60 years old need seven or more hours of sleep regularly per day for optimal health.
- Sleep-disordered breathing, including obstructive sleep apnea, is a detrimental condition affecting 15% of the
  population.
- Studies show that 85% of 725 troops returning home from Afghanistan and Iraq had a sleep disorder and the
  most common was obstructive sleep apnea (51%).
- Insufficient sleep impairs cognitive performance, which can increase the likelihood of motor vehicle and other transportation accidents, loss of work productivity, and medical errors.

#### LEGISLATIVE & POLICY RECOMMENDATIONS

- Continue to include "SLEEP DISORDERS" as a condition eligible for study through the Department of Defense Peer-Reviewed Medical Research Program (PRMRP) for FY 2018. Sleep researchers compete well for funding through the PRMRP over recent years due to the emerging understanding of the connection between military service, particularly post-traumatic stress disorder and traumatic brain injury, and insomnia, disrupted sleep-wake rhythms, and fatigue.
- Continue to provide meaningful funding increases for the Department of Veterans Affairs (VA) Medical
  and Prosthetic Research Program for FY 2018. Due to the connection between sleep health and the |
  aforementioned conditions that disproportionately impact military personnel and veterans, emerging and
  established VA-supported research projects focus on improving our understanding of sleep and sleep disorders
  with increasing frequency.
- Increase discretionary funding for the National Institutes of Health (NIH) to \$36.1 billion for FY 2018. The
  majority of NIH Institutes and Centers play a role in sleep and sleep disorders research as a result of the
  significant influence sleep has over other medical conditions and systems of the body. Sleep-related research
  activities at NIH are coordinated through the National Center on Sleep Disorders Research (NSCDR) housed
  within the National Heart, Lung, and Blood Institute.
- Support ongoing implementation of the NIH Sleep Disorders Research Plan and the sleep disorders
  surveillance activities at the Centers for Disease Control and Prevention (CDC). NSCDR is leading efforts to
  advance the recommendations and research goals on sleep and circadian rhythm disorders outlined by the 2011
  plan. CDC is working to enhance surveillance activities and gather better population-based data on the prevalence
  and health impacts of sleep and sleep disorders.