

American Nephrology Nurses Association

Weekly Capitol Hill Update – Tuesday, May 22, 2018

Congressional Schedule

Senate

- Senate meets at 10 am; to vote on nomination of Dana Baiocco to be commissioner of Consumer Product Safety Commission

House

- House meets at 10 am; set to consider S. 2155, which would relax provisions of Dodd-Frank law.
- House also set to consider S. 204, the “right to try” bill that would give patients with life-threatening diseases access to experimental treatments without FDA permission.

Legislative Update

- **Week in Review**
 - *House committee advances opioid bill senators call ‘weak’.* “A key House committee advanced an opioid prevention bill Wednesday that has come under fire by senators as a ‘weaker’ alternative to their version. The House Ways and Means Committee advanced four legislative packages and three standalone bills. Among them, the measure that has come under fire is the Synthetics Trafficking and Overdose Prevention Act, or STOP Act, which would require the U.S. Postal Service to scan incoming packages from overseas for opioids.”
 - Read more:
<https://www.washingtonexaminer.com/policy/healthcare/house-committee-advances-opioid-bill-senators-call-weak>
 - *Graham working on new ObamaCare repeal bill.* “Sen. Lindsey Graham (R-S.C.) said Wednesday he is working on a new version of his ObamaCare repeal-and-replace bill and has not given up on efforts to do away with the law despite Republicans’ failure last year. The effort appears to have little, if any, chance of passing this year. Republican leadership has made clear that it has moved on from the ObamaCare repeal effort, and the GOP has an even slimmer margin in

the Senate than they did last year when they failed to win enough votes for a bill.”

- Read more: <http://thehill.com/policy/healthcare/388000-graham-working-on-new-obamacare-repeal-bill>
- *Ryan: ‘Compromise’ in the works for controversial drug pricing bill.* “Speaker Paul Ryan (R-Wis.) said Thursday that a compromise is being worked out on a controversial bill aimed at lowering drug prices, boosting hopes from supporters that the bill could move forward. Ryan said the Energy and Commerce Committee and the Judiciary Committee are working out a compromise on the legislation, known as the Creates Act. He did not get into details on what that would be, but some Republicans have previously objected to the bill on the grounds that it would invite frivolous lawsuits against drug companies.”
 - Read more: <http://thehill.com/policy/healthcare/388196-ryan-compromise-being-worked-out-on-controversial-drug-pricing-bill>
- **Week Ahead**
 - *House to vote to send ‘right to try’ bill to Trump’s desk next week.* “The House will vote next week on Senate-passed legislation aimed at making it easier for sick patients to access experimental drugs – a big priority for President Trump, Vice President Pence and groups backed by conservative mega-donors Charles and David Koch. In August, the Senate passed Right to Try by unanimous consent. The bill, which Sen. Ron Johnson (R-Wis.) championed, lets sick patients request access to treatments the Food and Drug Administration (FDA) hasn’t yet approved.”
 - Read more: <http://thehill.com/business-a-lobbying/388124-house-to-vote-to-send-right-to-try-bill-to-trumps-desk-next-week>
 - *GOP Chairman plans hearings on Trump drug pricing proposals.* “House Ways and Means Committee Chairman Kevin Brady (R-Texas) said Tuesday that he plans to conduct hearings on some of President Trump’s new proposals to bring down drug prices. Brady said it is too early to tell if the committee will move legislation on the issue, but said he wanted to consider the ideas.”
 - Read more: <http://thehill.com/policy/healthcare/387829-gop-chairman-plans-hearings-on-trump-drug-pricing-proposals>

Regulatory and Administration Update

- *In first, FDA approves drug meant to mitigate symptoms of opioid withdrawal.* “The Food and Drug Administration on Wednesday approved for the first time a drug meant to mitigate the symptoms of opioid withdrawal – rather than an underlying dependency – giving American physicians a new tool to help patients begin treatment. The drug, lofexidine, will be manufactured by Kentucky-based US WorldMeds and marketed as Lucemyra.”
 - Read more: <https://www.statnews.com/2018/05/16/fda-approves-lofexidine-opioid-withdrawal/>

- **FDA calls out 39 drug companies for allegedly blocking access to generics.** “Johnson & Johnson’s Actelion Pharmaceuticals, Celgene, and Gilead Life Sciences are all potentially blocking generic drug makers from accessing samples of their products, along with three dozen other drug companies – according to new data out Thursday from the FDA intended to publicly shame them for what it calls ‘gaming tactics.’ The new list, which also includes Novartis, Pfizer, Valeant, and a host of other companies, is part of the Trump administration’s efforts to lower prescription drug prices that kicked off with a presidential address Friday. While broader regulatory and legislative changes must go through a complex and often lengthy process, top health officials have used their bully pulpits this week to call out a number of companies for what they consider bad behavior.”

 - Read more: <https://www.statnews.com/2018/05/17/fda-shames-drug-companies-generics-access/>
- **Kushner-backed health care project gets ‘devastating’ review.** “The first stage of a multibillion-dollar military-VA digital health program championed by Jared Kushner has been riddled with problems so severe they could have led to patient deaths, according to a report obtained by POLITICO. The April 30 report expands upon the findings of a March POLITICO story in which doctors and IT specialists expressed alarm about the software system, describing how clinicians at one of four pilot centers, Naval Station Bremerton, quit because they were terrified they might hurt patients, or even kill them.”

 - Read more: <https://www.politico.com/story/2018/05/11/kushner-backed-health-care-project-gets-devastating-review-535847>
- **Right-to-try bill headed for votes puts bigger burden on FDA to protect patients, Gottlieb says.** “The House is set to take up a controversial ‘right-to-try’ bill next week – and if it passes, the Food and Drug Administration will have to work harder to protect patients than it would if a different version of the legislation were advancing, Commissioner Scott Gottlieb told STAT in an interview. Gottlieb’s comments, made at FDA headquarters on Thursday, indicate that one of President Trump’s top lieutenants believes Congress is moving forward with a bill that contains less of his agency’s input than an alternative version of the bill – a more recent, updated bill that passed the House in March but ultimately stalled in the Senate.”

 - Read more: <https://www.statnews.com/2018/05/17/right-to-try-bill-gottlieb/>
- **NIH suspends study on benefits of alcohol after questions about industry involvement.** “The National Institutes of Health (NIH) has suspended a study into the benefits of moderate drinking following reports that agency officials lobbied the alcohol beverage industry to fund it. NIH Director Francis Collins said Thursday enrollment in the study was halted a week ago as officials investigate how funding was raised.”

 - Read more: <http://thehill.com/policy/healthcare/388159-nih-suspends-study-on-benefits-of-alcohol-after-questions-about-industry>
- **FDA looking at ways to include price info in drug ads, Gottlieb says, as questions loom.** “The commissioner of the Food and Drug Administration, Scott Gottlieb, said a proposal to have pharmaceutical companies include drug prices in advertisements has prompted

a series of questions, including exactly how consumers would benefit and whether the government can legally require the disclosures. In an interview with STAT, Gottlieb said an agency working group would consider questions like those as it seeks to implement one of the Trump administration's top proposals for lowering drug prices."

- Read more: <https://www.statnews.com/2018/05/18/scott-gottlieb-fda-interview-drug-pricing/>
- ***Trump nominates Robert Wilkie as VA secretary.*** "President Donald Trump announced Friday that he is nominating Robert Wilkie to lead the Department of Veterans Affairs, three weeks after his previous nominee withdrew from the confirmation process amid controversy. Wilkie is currently the undersecretary of defense for personnel and readiness but has been serving as the VA's acting secretary since the President fired VA Secretary David Shulkin in late March. But Trump said the announcement came as a surprise even to Wilkie."
 - Read more: <https://www.cnn.com/2018/05/18/politics/veterans-affairs-robert-wilkie/index.html>

Articles of Interest

- ***How a drugmaker gamed the system to keep generic competition away.*** "Revlimid appears to have caught the attention of Health and Human Services Secretary Alex Azar who used it as an example Wednesday – without naming it outright – of how some drug's prices rise with impunity. He said the copay for the average senior taking the drug rose from \$115 to about \$690 per month in the last year. Celgene can keep raising the price of Revlimid because the drug has no competition. It's been around for more than a decade and its original patent expires next year. But today it looks like another four years could pass with no generic competitor to Revlimid."
 - Read more: <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away>
- ***A smarter way for the world to eat better.*** "Combating the rise in obesity is a major health challenge here in America and around the world. According to the Trust For America's Health and the Robert Wood Johnson Foundation, obesity rates have increased in all 50 states since 1990; the Centers for Disease Control and Prevention notes obesity is associated with the leading causes of death in the U.S. and worldwide. Instead of penalizing consumers [through beverage taxes], local governments and public health officials should work with private-sector leaders to empower people to make balanced nutrition decisions that work for their families. The alternative – as we've seen in Berkeley, Philadelphia, Mexico and around the world – simply doesn't work in the fight to end obesity."
 - Read more: <https://morningconsult.com/opinions/smarter-way-world-eat-better/>
- ***2018 Senior Report.*** "According to the United States Census Bureau, adults aged 65 and older now comprise more than 15 percent of the total population. By 2030, that number will climb significantly to 20 percent. The growing number of seniors and the

corresponding projected growth in the use of clinical and community services will only deepen their impact on the overall health status of the nation. As community leaders, policymakers and public health professionals prepare to address these population shifts, *America's Health Rankings*® offers a suite of readily available health data to help inform important decisions and community health efforts. The 2018 *America's Health Rankings Senior Report* provides the latest check-up on the health and well-being of our nation's seniors. Using 34 measures of senior health, the report highlights successes and challenges this population faces on a national and state-by-state basis. This year's report highlights two supplemental measures – the suicide rate among seniors as well as a new measure to identify locations where seniors are at higher risk of social isolation.”

- Read more: <https://www.americashealthrankings.org/learn/reports/2018-senior-report/executive-summary>
- ***Vermont becomes first state to permit drug imports from Canada.*** “Vermont Republican Gov. Phil Scott Wednesday signed legislation making his state the first to legalize importing prescription drugs from Canada, an idea President Donald Trump's top health officials oppose that's also drawn fierce opposition from the pharmaceutical industry. A spokeswoman for Scott said he signed the bill Wednesday morning. The measure had overwhelming support in the Democratic-controlled legislature and is one of the most aggressive attempts by a state to tackle rising drug prices that critics say are crippling state finances.”
 - Read more: <https://www.politico.com/story/2018/05/16/vermont-drug-imports-canada-546107>
- ***A darker side to diabetes: 51% of patients have been treated for stress or mental health issues, according to new survey by Ieso.*** “Three quarters (75%) of young adults (16-34) believe that their mental health has been negatively affected by their diabetes. Almost half (46%) say that more awareness of diabetes-specific mental health issues would help prevent high levels of stress, anxiety and depression and other mental health problems, associated with having diabetes. 43% say mental health education and assessment should be integrated into on-going diabetes health care.”
 - Read more: <http://www.prnewswire.co.uk/news-releases/a-darker-side-to-diabetes-51-of-patients-have-been-treated-for-stress-or-mental-health-issues-according-682509761.html>
- ***Nurse overtime harms professional collaboration.*** “After one hour of overtime, nurse to nurse collaboration drops from the 50th percentile to the 30th percentile. Nurses often work long, irregular hours and unexpected overtime which puts them at risk for fatigue and sleep deprivation and can lead to impaired emotional, social, and cognitive processing. This, in turn, may hurt nurses’ ability to collaborate.”
 - Read more: <http://www.healthleadersmedia.com/nurse-leaders/nurse-overtime-harms-professional-collaboration>
- ***Opioid deaths boost organ transplant availability.*** “The increase in opioid-related deaths has created a grim harvest of vital organs for transplant, a study shows. Researchers found a more than 10-fold increase in the proportion of donors who died

from drug overdoses between the years 2000 and 2016 in the United States, from 1.2% (59) to 13.7% (1,029)."

- Read more: <http://www.healthleadersmedia.com/quality/opioid-deaths-boost-organ-transplant-availability>
- **Researchers take key step in growing human organs in laboratory.** "Researchers have learned that precursor cells for skeletal muscles actually also give rise to neurons, blood vessels, blood cells and immune cells, pushing science one step closer to generating body parts in a laboratory."
 - Read more: https://www.eurekalert.org/pub_releases/2018-05/osu-rtk051518.php
- **First Lady Melania Trump hospitalized after treatment for kidney condition.** "First lady Melania Trump is expected to be hospitalized all week after undergoing a surgical procedure to treat a kidney condition. Communications director Stephanie Grisham tells NPR the first lady is "is doing well." In a statement, she said Trump underwent an embolization procedure on Monday morning to treat a benign kidney condition. She said the procedure was successful and without complications."
 - Read more: <https://www.npr.org/2018/05/14/611077210/first-lady-melania-trump-hospitalized-after-treatment-for-kidney-condition>
- **More patients are taking home recordings of their doctor visits. But who else could listen?** "Doctors across the U.S. have begun doing what once seemed unthinkable in a litigious health care environment: recording their medical conversations with patients and encouraging them to review the audio at home. The rationale for the practice is as simple as the smartphone technology that enables it: having a recording improves patients' understanding and recall of their doctor visits and helps them adhere to treatment regimens. Now the increasing power of artificial intelligence is promising to bring this technical capability to a new level — potentially offering big rewards, and risks, for patients and caregivers."
 - Read more: <https://www.statnews.com/2018/05/18/artificial-intelligence-recording-doctor-visits/>