

## American Nephrology Nurses Association

Weekly Capitol Hill Update – Tuesday, June 11, 2019

### Congressional Schedule

#### Senate

- Senate is in Session all week.

#### House

- House is in session until June 14.

### Legislative Update

- **Week in Review**
  - *Trump administration limits research using fetal tissue:* “The US Department of Health and Human Services said Wednesday it will not renew a fetal tissue research contract with the University of California, San Francisco that expired today. The decision concludes a review of research using tissue from aborted fetuses. The agency also announced measures to limit future research involving human fetal tissue from elective abortions. "Promoting the dignity of human life from conception to natural death is one of the very top priorities of President Trump's administration," a statement from Health and Human Services said.”
    - <https://www.cnn.com/2019/06/05/health/hhs-fetal-tissue-research-bn/index.html>
- **Week Ahead**
  - *Rep. Eliot Engel introduces legislation to provide grants to better understand and reduce gestational diabetes:* “U.S. Representatives Eliot L. Engel (NY-16) and Michael C. Burgess, M.D. (TX-26) have reintroduced the Gestational Diabetes (GEDI) Act, legislation focused on reducing the incidence of gestational and type 2 diabetes in women and children. Gestational diabetes occurs in pregnant women who have never had diabetes, but have high blood glucose (sugar) levels during their pregnancies and cannot make and use the insulin they need to process

their elevated levels of glucose. Gestational diabetes can have long-term health consequences for affected babies, including the development of type 2 diabetes and preterm respiratory distress syndrome.

- <https://engel.house.gov/latest-news/engel-burgess-reintroduce-the-gestational-diabetes-act/>
  - <https://www.congress.gov/bill/116th-congress/house-bill/3109/text?q=%7B%22search%22%3A%5B%22HR+3109%22%5D%7D&r=1&s=1>
- ***Growing Hack of Health-Care Data Gets Scrutiny From Congress:*** “A hack of health-care data involving a medical bill collector and two major diagnostics companies has grown to almost 20 million people, and is now attracting more questions from key members of Congress. American Medical Collection Agency, an Elmsford, New York-based collections firm, has now been identified by two large medical companies as the victim in a large health-care data breach. On Tuesday, Laboratory Corporation of America Holdings said that 7.7 million patients’ accounts at AMCA were stored in the vulnerable computer system. The disclosure follows a similar warning by Quest Diagnostics Inc. that 11.9 million people were exposed.”
    - <https://www.bloomberg.com/news/articles/2019-06-05/growing-hack-of-health-care-data-attracts-scrutiny-of-congress>

### Regulatory and Administration Update

- ***CDC investigating large cluster of peritonitis cases in peritoneal dialysis patients:*** “The Centers for Disease Control and Prevention (CDC) and two health departments are investigating a large cluster of peritonitis cases among patients undergoing peritoneal dialysis. Many of the peritonitis events under investigation were caused by *Serratia marcescens* or other gram-negative pathogens. CDC is requesting U.S. clinicians to report peritonitis cases in peritoneal dialysis patients treated by the same center that meet the following criteria: Two or more patients with peritonitis caused by *Serratia* spp. at the same center since January 1, 2019, or An increase in peritonitis caused by gram-negative organisms at the center”
  - <https://www.kidneynews.org/policy-advocacy/leading-edge/cdc-investigating-large-cluster-of-peritonitis-cases-in-peritoneal-dialysis-patients>
- ***VA study backs use of physician assistants, nurse practitioners in diabetes care:*** “Veterans Affairs patients with diabetes have similar health outcomes regardless of whether their primary provider is a physician, nurse practitioner (NP), or

physician assistant (PA), according to a Durham VA Health Care System study. The results appear in the June 2019 edition of the Journal of the American Academy of Physician Assistants. "Our study found that there were not clinically important differences in intermediate diabetes outcomes for patients with physicians, NPs, or PAs in both the usual and supplemental provider roles, providing additional evidence for the role of NPs and PAs as primary care providers," said Dr. George Jackson, senior author on the paper.

- [https://www.eurekalert.org/pub\\_releases/2019-06/varc-vs060719.php](https://www.eurekalert.org/pub_releases/2019-06/varc-vs060719.php)
- ***Government to start posting list of troubled nursing homes:*** "In a turnabout, the government said Wednesday it will start posting a list of some 400 troubled nursing homes, days after senators released the "secret" document along with a report questioning oversight of poor-quality facilities. Dr. Kate Goodrich, chief medical officer with the Centers for Medicare and Medicaid Services, said the agency soon will post the list and update it regularly. She didn't set a date.
  - <https://www.apnews.com/c8e1e70253fb405e8fe13cd7b2eda70f>
- ***V.A. Prepares for Major Shift in Veterans' Health Care:*** "The Department of Veterans Affairs on Thursday will begin allowing a broad section of its nine million enrollees to seek medical care outside of traditional V.A. hospitals, the biggest shift in the American health care system since the passage of the Affordable Care Act nearly a decade ago. While department officials say they are ready, veterans groups and lawmakers on Capitol Hill have expressed concerns about the V.A., which has been dogged for years by problems with its computer systems. They worry that the department is not fully prepared to begin its new policy, which Congress adopted last year to streamline and expand the way veterans get care.
  - <https://www.nytimes.com/2019/06/05/us/politics/va-health-care-veterans.html>
- ***NIH funds clinical trials using genomics to treat chronic diseases:*** "The National Institutes of Health will fund clinical trials to assess the benefits, applicability and efficacy of applying genomic medicine interventions to improve management of diseases such as high blood pressure, depression and chronic pain. The trials are part of the second phase of the Implementing Genomics in Practice (IGNITE) Network with a total investment of \$42 million over five years, pending the availability of funds. The trials will begin in 2020."
  - <https://www.nih.gov/news-events/news-releases/nih-funds-clinical-trials-using-genomics-treat-chronic-diseases>
- ***FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices:*** "The U.S. Food and Drug Administration today permitted marketing of the

Tandem Diabetes Care t: Slim X2 insulin pump with interoperable technology (interoperable t: Slim X2) for delivering insulin under the skin for children and adults with diabetes. This new type of insulin pump, referred to as an alternate controller enabled (ACE) infusion pump, or ACE insulin pump, is the first interoperable pump, meaning it can be used with different components that make up diabetes therapy systems, allowing patients to tailor their diabetes management to their individual device preferences. Diabetes therapy systems may be comprised of an ACE insulin pump and other compatible medical devices, including automated insulin dosing (AID) systems, continuous glucose monitors (CGMs), blood glucose meters or other electronic devices used for diabetes management.”

- <https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-insulin-pump-intended-allow-patients-customize-treatment-through>

### Articles of Interest

- ***Study Published in Journal of Clinical Investigation Insight Demonstrates Ability to Predict Early Rejection in Kidney Transplant with FractalDx Portfolio Technology:*** “Renalytix AI plc (AIM: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announced today that positive study results have been published in the Journal of Clinical Investigation (JCI) Insight<sup>1</sup>. These results show FractalDx portfolio technology can accurately predict early acute kidney rejection in transplant patients. Early detection of acute transplant rejection is a critical unmet medical need that directly affects transplant success and long-term patient survival. In addition, the published results suggest that FractalDx can be used to personalize and potentially optimize the administration of immunosuppression therapy in kidney transplant patients. This could mitigate toxic side effects and damage to the transplanted kidney arising from excessive dosing.”
  - <https://www.biopharmadive.com/press-release/20190610-study-published-in-journal-of-clinical-investigation-insight-demonstrates-a/>
- ***Lannett Announces Initiation Of Human Clinical Trial Of Biosimilar Insulin Glargine Versus Us Lantus®:*** “Lannett Company, Inc. (NYSE: LCI) today announced the commencement of a human clinical trial of biosimilar insulin glargine, a product the company is co-developing with its strategic alliance partners within the HEC Group of companies (HEC). The trial, being conducted in South Africa, is the first clinical study to directly compare the Lannett/HEC insulin glargine to US Lantus® as part of the effort to file a biosimilar Biologics License Application with the U.S. Food and Drug Administration. Insulin glargine is a long-acting insulin used to treat adults with Type 2 diabetes, as well

as adults and pediatric patients with Type 1 diabetes, for the control of high blood sugar.”

- <https://www.prnewswire.com/news-releases/lannett-announces-initiation-of-human-clinical-trial-of-biosimilar-insulin-glargine-versus-us-lantus-300862087.html>

- ***Lilly's ultra rapid lispro provided similar A1C reductions compared to Humalog® (insulin lispro), with superior post-meal blood glucose reductions:*** “Two phase 3 studies show that Eli Lilly and Company's (NYSE: LLY) ultra rapid lispro (URLi) provided non-inferior A1C reductions compared to Humalog® (insulin lispro) at 26 weeks in people with type 1 and type 2 diabetes. The data from these treat-to-target studies showed URLi also significantly reduced the rise in blood glucose one hour and two hours after a test meal compared to Humalog.<sup>1,2</sup> Additional data from the study in people with type 1 diabetes demonstrated URLi significantly improved glucose time in range during the day.<sup>3</sup> URLi is an investigational novel mealtime insulin formulation being developed to better manage blood glucose levels. These data and several other studies were presented at the American Diabetes Association's® 79th Scientific Sessions®.”
  - <https://www.prnewswire.com/news-releases/lillys-ultra-rapid-lispro-provided-similar-a1c-reductions-compared-to-humalog-insulin-lispro-with-superior-post-meal-blood-glucose-reductions-300864210.html>
- ***Serota retiring as Blue Cross and Blue Shield Association CEO:*** “The Blue Cross and Blue Shield Association announced Wednesday its longtime CEO will retire at the end of 2020. The Blues board of directors is working to identify Scott Serota's replacement to ensure a smooth transition, according to the release. For the time being, Serota will continue to focus on the organization's business and policy priorities. Serota joined the federation of 36 independent Blues companies, in 1996 and assumed his current role in 2000.
  - <https://www.modernhealthcare.com/people/serota-retiring-blue-cross-and-blue-shield-association-ceo>
- ***Including Family Caregivers In Seriously Ill Veterans' Care: A Mixed-Methods Study:*** “Family caregivers often serve as unpaid members of the home and community-based care workforce for people with serious illness; as key partners in the home-clinic continuum, they should be included in health care teams. The Campaign for Inclusive Care is an initiative within the Veterans Affairs health care system to improve provider practices for including caregivers of military members in treatment planning and decisions. We defined inclusive care using a literature review, provider interviews, and a caregiver survey. We found that inclusive care involves clear definition of the caregiver role, system policies for inclusion, assessment of caregivers' capacity, explicit involvement of caregivers,

and mutuality in caregiver-provider communication. We recommend solutions based on this definition that can inform development of a national caregiver strategy, required of the Department of Health and Human Services by the Recognize, Assist, Include, Support, and Engage Family Caregivers Act of 2018”

- <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00012>
- ***Abbott and Tandem in the spotlight at diabetes meeting:*** “Leading medical device companies have arrived in San Francisco for the American Diabetes Association (ADA) meeting, setting the stage for updates that will shape the continuous glucose monitor (CGM) and insulin pump markets. Companies including Dexcom and Roche released news ahead of the event. Roche partnered with diabetes care platform GlucoMe, while Dexcom entered into a diabetes data exchange with Companion Medical.”
  - <https://www.medtechdive.com/news/abbott-and-tandem-in-the-spotlight-at-diabetes-meeting/556417/>
- ***Eastern Nephrology Associates Announces Merger with Southeastern Nephrology Associates:*** “Eastern Nephrology Associates (ENA) has announced its merger with Southeastern Nephrology Associates (SENA) effective June 1st. The new organization will operate as Eastern Nephrology Associates. The merger joins two prominent kidney care physician practices which will include 27 physician partners, 4 associate physicians, and 14 advanced practitioners. Collectively, the practice will manage more than 2200 dialysis patients, operate two vascular access centers, provide a fully integrated laboratory, manage kidney transplant patients, and oversee a robust clinical trials program.”
  - <https://www.prnewswire.com/news-releases/eastern-nephrology-associates-announces-merger-with-southeastern-nephrology-associates-300862800.html>