HHS | Hart Health Strategies Inc.

Health Policy Briefing

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Senate to Begin Impeachment Trial on Tuesday

Senate Majority Leader Mitch McConnell (R-Ky.) announced that the Senate will start debating an organizing resolution to begin President Trump's impeachment trial on Tuesday. The organizing resolution will determine time limits for opening arguments from the House impeachment managers, opening arguments for the president's defense team, and for senators to ask questions. It is unclear at this time how long the trial will last. Negotiations are underway regarding what other Senate business may continue during impeachment. It is hoped that committees will be allowed to hold hearings in the morning (if the proceedings are bipartisan) and that cosponsors may be added with unanimous consent. The introduction of bills and resolutions would require consent as well. However, legislative and executive hotlines will not be run during impeachment.

The House of Representatives has adjourned for a week-long Martin Luther King Day recess and will return on January 27.

Hart Health Strategies Inc. Releases Timeline of Key 2020 Dates

Hart Health Strategies Inc. has prepared a timeline of key dates in 2020 which you may find helpful in your planning for the year. The timeline is available here.

Inside

Hoyer Outlines 2020 Democratic Agenda

In an interview with ***CQ Roll Call*** last week, House Majority Leader Steny Hoyer (D-Md.) outlined his legislative priorities for the second session of the 116th Congress. According to Rep. Hoyer, House Democrats plan to pursue legislation related to health care, infrastructure, and the climate, while also attempting to fully fund the federal government. In addition to continuing to pursue solutions to lower prescription drug prices, Democrats also hope to pass legislation to strengthen the Affordable Care Act (ACA) and protections for preexisting conditions. Hoyer also mentioned the topics of maternal mortality, youth vaping, and health care affordability as important priorities. Democrats plans to reserve the month of June to pass appropriations legislation through the House, with the goal of fully funding the government before the start of fiscal year on October 1, 2020 (FY) 2021 – an achievement that has not occurred since 1996.

Speaker Nancy Pelosi (D-Calif.) has stated that the House of Representatives will begin work to address the issue of surprise insurance gaps when it returns from the week-long Martin Luther King day recess on January 27. Bipartisan leadership of the House Ways and Means and Energy and Commerce committees are still in negotiations on competing versions of legislation to bring a compromise bill to the floor.

HRSA Releases Latest Nursing Workforce Data

The Health Resources and Services Administration (HRSA) has released new data from the National Sample Survey of Registered Nurses (NSSRN). The NSSRN has been collected since 1977 and is the main source of information on the nursing workforce.

HHS Personnel Departures

Chief Medical Officer at the Centers for Medicare and Medicaid Services (CMS) Kate Goodrich has announced that she will be leaving the agency next month. Dr. Goodrich also serves as the Director of the Center for Clinical Standards and Quality, and she has led the Quality Measurement and Value-Based Incentives Group since 2012. During her time at CMS, Dr. Goodrich has been responsible for quality measurement and improvement, public reporting work, the marketplace quality portfolio, value-based incentives programs, implementation of the Medicare Access and CHIP Reauthorization Act (MACRA), and comparative effectiveness research. She plans to join Humana Corp. as the company's next senior vice president, overseeing the insurer's data, trend, and analysis work. Jean Moody-Williams will serve as acting head of the CMS clinical and quality center upon her departure.

Chief Data Officer at the U.S. Department of Health and Human Services (HHS) Mona Siddiqui also announced that she would be leaving her post at the administration to become a vice president at Humana. Siddiqui had held the position at HHS since 2017. During this time, she worked to streamline the department's data operations and led its artificial intelligence (AI) strategy. Her replacement was not immediately announced.

E&C Press FDA on Complex Generics Approvals

Bipartisan leadership of the House Energy and Commerce Committee has written to Commissioner of Food and Drugs Stephen Hahn, M.D. requesting information on the agency's process for the approval of complex generic drugs. "The length of time leading to the approval of some recently approved complex generics raises questions of whether additional actions may be necessary to encourage the development of these products," the lawmakers state. They request a response from the Food and Drug Administration (FDA) by January 31. The letter was sent by Chairman Frank Pallone (D-N.J.), Ranking Member Greg Walden (R-Ore.), Health Subcommittee Chairwoman Anna G. Eshoo (D-Calif.), Ranking Member Michael Burgess, M.D. (R-Texas), Oversight and Investigations Subcommittee Chair Diana DeGette (D-Colo.), and Ranking Member Brett Guthrie (R-Ky.).

JAMA Examines Changes in FDA Drug Approvals

A new report from the Journal of the American Medical Association (JAMA) indicates that the FDA is increasingly approving new drugs with fewer clinical trials. The analysis found that the number of drugs approved based on two pivotal trials decreased from 81 percent in 1995-1997 to 53 percent in 2015-2017. The number of drug applications including at least one pivotal trial in comparison to another drug decreased from 44 percent to 29 percent. The report also finds that an increasing number of companies are testing their products against a placebo or using historical data for evaluation.

Court of Appeals Considers White House DTC Advertising Rule

The U.S. Court of Appeals for the District of Columbia Circuit appear unlikely to reverse a July district court ruling that the U.S. Department of Health and Human Services (HHS) does not have the authority to require pharmaceutical manufacturers to disclose list prices in direct-to-consumer (DTC) advertising. Members of the three-judge panel questioned whether the regulation would increase Medicare and Medicaid administrative efficiency as HHS has argued. They also expressed doubt that the proposal would actually help control drug spending and noted that it would still not allow for consumers to evaluate the relative costs of different drugs. Merck, Eli Lilly, Amgen, and the Association of National Advertisers are suing HHS, asserting that the policy would confuse patients and discourage them from accessing treatment.

EPA Revises EtO Regulation

The Environmental Protection Agency (EPA) has revised a regulatory notice that sought information about how companies could use lower levels of ethylene oxide (EtO) in the sterilization of medical devices following objections from the FDA. The FDA argued that the EPA only has authority over releases of the chemical into the air, not over how much of it is used in sterilization plants. The EPA is attempting to update its emission standards in light of findings that EtO is at least 30 times more carcinogenic than previously thought.

FDA Committees Recommend Against New Opioid Approvals

The Anesthetic and Analgesic Drug Products and the Drug Safety and Risk Management advisory committees voted unanimously against the approval of Nektar's oxycodegol last week. Oxycodegol is an opioid intended for the management of chronic lower back pain in adults for whom other treatment options are inadequate. It is one of the first products to be reviewed since the FDA's issuance of a draft guidance regarding the consideration of broader public health risks in the approval of opioid medications. Nektar argued that its drug was less likely to be abused than currently-approved opioid products, stating that oxycodegol is designed to cross the blood-brain barrier slowly to reduce the potential for abuse or misuse. The FDA, however, asserted that the adverse events observed as a result of oxycodegol indicate an abuse potential similar to oxycodone. Several committee members acknowledged that oxycodegol may offer increased safety potential, but that Nektar needs to provide better supporting data. Other advisory committee members appeared hesitant about the introduction of any new opioid drugs to the market.

The advisory committees later deadlocked on a decision over whether to approve a combination pain drug from Esteve Pharmaceuticals. The product combines the non-opioid pain reliever celecoxib with tramadol, an opioid with low abuse potential. The drug's sponsor argued that the formulation could be an alternative to more potent products. Advisory committee members, however, raised concerns about its efficacy. The FDA is not obligated to follow the recommendations of its advisory committees, but often does.

New Data Uncovered on Nationwide Opioid Distribution

Newly released federal data shows that more than 100 billion doses of oxycodone and hydrocodone were shipped nationwide between 2006 and 2014, 24 billion doses more than previously realized. While the figures collected by the Drug Enforcement Administration (DEA) between 2006 and 2012 were obtained and released by the ***Washington Post*** last year, the numbers for 2013 and 2014 were just made public last week as a part of a lawsuit against the opioid industry. The data traces the number of pills from the manufacturer to the distributor and to the pharmacies across the country. West Virginia, Kentucky, South Carolina, and Tennessee received the most opioids per person over the nine-year period.

Senate Passes Fentanyl Analogues Legislation

The Senate passed the ***Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act*** (S. 3201) by unanimous consent last week. The bill would extend for 15 months the Drug Enforcement Administration's (DEA) authority to regulate all new fentanyl analogues as Schedule I drugs. The previous order was scheduled to expire in February. A deal was reached on a temporary extension by Senate Judiciary Chairman Lindsey Graham (R-S.C.) and Ranking Member Dianne Feinstein (D-Calif.), and Sen. Dick Durbin (D-Ill.), who had expressed concerns that a permanent measure would negatively impact research on pain medications. The administration urged passage of the bill during a hearing before the House Energy and Commerce Health Subcommittee on cannabis last week. During the hearing, the panel considered six marijuana-related bills and heard testimony from the DEA, the FDA's Center for Drug Evaluation and Research (CDER), and the National Institute on Drug Abuse (NIDA). Relatedly, the House Judiciary Subcommittee on Crime, Terrorism, and Homeland Security has announced a hearing titled "Fentanyl Analogues: Perspectives on Classwide Scheduling" on Tuesday, January 28 at 10:00 am EST.

Education and Labor Marks Up Pregnancy Discrimination Bill

The House Education and Labor Committee has passed legislation that would expand protections against discrimination for pregnant employees. The ***Pregnant Workers Fairness Act*** (H.R. 2694) was advanced by a vote of 29-17. It would require that businesses employing more than 15 people provide reasonable accommodation to pregnant workers, while allowing them to continue working throughout pregnancy and after childbirth. Employers and employees would negotiate such accommodations through a process established by the Americans with Disabilities Act. Employees seeking accommodation would be required to communicate their pregnancy or other related conditions to their employer and ask for an accommodation. Reps. James Comer (R-Ky.) and Elise Stefanik (R-N.Y.) were the only GOP panel members to vote in support of the bill. Other Republicans on the committee raised concerns about the impact of the bill on religious-affiliated employers.

AAPS Suing Over Vaccine Misinformation Oversight

The Association of American Physicians and Surgeons (AAPS) is suing Rep. Adam Schiff (D-Calif.) accusing him of pressuring technology companies like Google, Facebook, Twitter, and Amazon to curb medically inaccurate information about the safety and effectiveness of vaccines. The group, which is skeptical of the necessity of mandatory vaccinations, is asking that the U.S. District Court of D.C. force Rep. Schiff to delete all materials related to his oversight efforts on medically inaccurate vaccine information. AAPS argues that the actions taken by the tech giants in response to letters from Rep. Schiff have negatively impacted its reputation and reduced traffic to its website.

Democrats Question DOL About Mental Health Parity

Democrats on the House Committee on Education and Labor have written to Labor Department Assistant Secretary Preston Rutledge regarding the enforcement of federal mental health parity law. The letter asserts that the Employee Benefits Security Administration (EBSA) is not sufficiently providing mental health and substance use disorder (SUD) care under the law. In the letter, the members request documents from EBSA outlining steps the agency is taking to safeguard such benefits and ensure that plans comply with the Employee Retirement Income Security Act (ERISA).

Lawmakers Request Review of IHS Facilities

Bipartisan leadership of the House Energy and Commerce Committee has sent a letter to the Government Accountability Office (GAO) requesting that the agency review patient access to quality health care in the Indian Health Service (IHS). The letter asserts that IHS' aging infrastructure may be negatively impacting the outcome of patient care. The average age of IHS-owned facilities is 35 years, while the average age of private-sector health care facilities is 10 years. Chairman Frank Pallone (D-N.J.), Ranking Member Greg Walden (R-Ore.), Rep. Raul Ruiz, M.D. (D-Calif.), and Rep. Markwayne Mullin (R-Okla.) ask that the GAO review efforts to maintain, renovate, or replace aging infrastructure and medical equipment, as well as the implementation of new IHS programs and technologies to increase capacity to provide patient care.

E&C Republicans Request information on AD/ADRD Research

Republicans on the House Energy and Commerce Committee are asking federal health agencies for information about what they are doing to advance Alzheimer's disease treatments and cures. In a letter sent to HHS Deputy Assistant Secretary for Planning and Evaluation Brenda Destro, Director of the Centers for Disease Control and Prevention (CDC) Robert R. Redfield, M.D, and National Institutes of Health (NIH) Director of National Institute on Aging (NIA) Richard J. Hodes, M.D., the lawmakers request details on what barriers stand in the way of an Alzheimer's Disease-Related Dementias (AD/ADRD) cure, and what Congress can do to help overcome such barriers. The letter was signed by Ranking Member Greg Walden (R-Ore.), Oversight and Investigations Subcommittee Ranking Member Brett Guthrie (R-Ky.), and Health Subcommittee Ranking Member Michael Burgess, M.D. (R-Texas).

USMCA Approved by Senate, Awaits Canadian Passage

The Senate passed the legislation to ratify the U.S.-Mexico-Canada Agreement (USMCA) last week by a vote of 89-10. Minority Leader Chuck Schumer (D-N.Y.), Bernie Sanders (I-Vt.), Kirsten Gillibrand (D-N.Y.), Cory Booker (D-N.J.), Kamala Harris (D-Calif.), Ed Markey (D-Mass.), Sheldon Whitehouse (D-R.I.), Jack Reed (D-R.I.), Brian Schatz (D-Hawaii), and Pat Toomey (R-Pa.). voted against the proposed trade pact. The Democrats who voted against the measure cited concerns about weak environmental standards, while Sen. Toomey argued that the agreement would increase prices for American consumers. The overhaul of the North American Free Trade Agreement (NAFTA) was approved by the Senate Finance Committee and six other panels earlier in the week. It will now be sent to the President's desk for his signature but will not go into full effect until it is approved by Canada. The Canadian parliament will reconvene later this month, where the deal is expected to pass. The USMCA is projected to add 0.35 percent to the U.S. gross domestic product (GDP) after six years.

Recently Introduced Health Legislation

H.R.5575 — To amend the Employee Retirement Income Security Act of 1974, title XXVII of the Public Health Service Act, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to provide for 3 primary care visits and 3 behavioral health care visits without application of any cost-sharing requirement; Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Energy and Commerce; Education and Labor; Ways and Means

H.R.5578 — To provide for the mandatory recall of drugs regulated by the Food and Drug Administration; Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Committees: House - Energy and Commerce

H.R.5582 — To amend titles XIX and XXI of the Social Security Act to require hospitals and certain other participating providers under Medicaid or the Children's Health Insurance Program to disclose the provider's policy on parental consent for the provision, withdrawal, or denial of life-sustaining treatment for minors, and for other purposes; Sponsor: Rep. Murphy, Gregory [R-NC-3]; Committees: House - Energy and Commerce

H.R.5587 — To amend the Federal Food, Drug, and Cosmetic Act with respect to the regulation of hemp-derived cannabidiol and hemp-derived cannabidiol containing substances; Sponsor: Rep. Peterson, Collin C. [D-MN-7]; Committees: House - Energy and Commerce; Agriculture

H.R.5590 — To amend title 38, United States Code, to treat certain individuals who served in Vietnam as a member of the armed forces of the Republic of Korea as a veteran of the Armed Forces of the United States for purposes of the provision of health care by the Department of Veterans Affairs; Sponsor: Rep. Cisneros, Gilbert Ray, Jr. [D-CA-39]; Committees: House - Veterans' Affairs

S.3182 — A bill to direct the Secretary of Veterans Affairs to carry out the Women's Health Transition Training pilot program through at least fiscal year 2020, and for other purposes; Sponsor: Sen. Sullivan, Dan [R-AK]; Committees: Senate - Veterans' Affairs

H.Res.794 — Supporting the designation of January 2020 as "National One Health Awareness Month" to promote awareness of organizations focused on public health, animal health, and environmental health collaboration throughout the United States and to recognize the critical contributions of those organizations to the future of the United States; Sponsor: Rep. Schrader, Kurt [D-OR-5]; Committees: House - Oversight and Reform

H.R.5596 — To amend the Internal Revenue Code of 1986 to expand and improve health savings accounts, and for other purposes; Sponsor: Rep. Roy, Chip [R-TX-21]; Committees: House - Ways and Means

S.3193 — A bill to amend the Controlled Substances Act to list fentanyl-related substances as schedule I controlled substances, and for other purposes; Sponsor: Sen. Portman, Rob [R-OH]; Placed on Senate Legislative Calendar under Read the First Time.

H.R.5610 — To amend title 38, United States Code, to expand the list of diseases presumed to have a service connection to exposure to certain herbicide agents; Sponsor: Rep. Harder, Josh [D-CA-10]; Committees: House - Veterans' Affairs

H.R.5611 — To promote State requirements for local educational agencies and public elementary and secondary schools relating to the prevention and treatment of concussions suffered by students; Sponsor: Rep. DeSaulnier, Mark [D-CA-11]; Committees: House - Education and Labor

H.R.5616 — To require the Secretary of Veterans Affairs to submit to Congress reports on patient safety and quality of care at medical centers of the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. McKinley, David B. [R-WV-1]; Committees: House - Veterans' Affairs

H.R.5619 — To authorize a pilot program to expand and intensify surveillance of self-harm in partnership with State and local public health departments, to establish a grant program to provide self-harm and suicide prevention services in hospital emergency departments, and for other purposes; Sponsor: Rep. Stewart, Chris [R-UT-2]; Committees: House - Energy and Commerce

S.3194 — A bill to establish a program ensuring access to accredited continuing medical education for primary care physicians and other health care providers at Federally-qualified health centers and rural health clinics, to provide training and clinical support for primary care providers to practice at their full scope and improve access to care for patients in underserved areas; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.3195 — A bill to require the Secretary of Defense and the Secretary of Veterans Affairs to review the records of former members of the Armed Forces who die by suicide within one year of separation from the Armed Forces and to require the Secretary of Veterans Affairs to submit a report on the REACH VET program; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Veterans' Affairs

S.3198 — A bill to authorize a pilot program to expand and intensify surveillance of self-harm in partnership with State and local public health departments, to establish a grant program to provide self-harm and suicide prevention services in hospital emergency departments, and for other purposes; Sponsor: Sen. Reed, Jack [D-RI]; Committees: Senate - Health, Education, Labor, and Pensions

S.3200 — A bill to amend the Internal Revenue Code of 1986 to permit high deductible health plans to provide chronic disease prevention services to plan enrollees prior to satisfying their plan deductible; Sponsor: Sen. Thune, John [R-SD]; Committees: Senate – Finance

H.R.5631 — To authorize the Secretary of Health and Human Services to provide grants to medical and other health profession schools to expand or develop education and training programs for substance use prevention and treatment, and for other purposes; Sponsor: Rep. Kim, Andy [D-NJ-3]; Committees: House - Energy and Commerce

H.R.5632 — To establish procedures regarding the approval of opioid drugs by the Food and Drug Administration; Sponsor: Rep. Kim, Andy [D-NJ-3]; Committees: House - Energy and Commerce

H.R.5633 — To amend title III of the Public Health Service Act to direct the Secretary, acting through the Director of the Centers for Disease Control and Prevention, to provide for a public education campaign for the promotion outreach and education campaign to raise public awareness of synthetic opioids; Sponsor: Rep. Kim, Andy [D-NJ-3]; Committees: House - Energy and Commerce

H.R.5637 — To amend title 38, United States Code, to establish presumptions of service connection for diseases associated with firefighting; Sponsor: Rep. Spanberger, Abigail Davis [D-VA-7]; Committees: House - Veterans' Affairs

H.R.5640 — To require the Federal Communications Commission to incorporate data on maternal health outcomes into its broadband health maps; Sponsor: Rep. Butterfield, G. K. [D-NC-1]; Committees: House - Energy and Commerce

H.R.5648 — To direct the Department of Veterans Affairs to furnish stellate ganglion block to veterans with post-traumatic stress disorder; Sponsor: Rep. Perry, Scott [R-PA-10]; Committees: House - Veterans' Affairs

S.3201 — A bill to extend the temporary scheduling order for fentanyl-related substances, and for other purposes; Sponsor: Sen. Graham, Lindsey [R-SC]; Latest Action: Message on Senate action sent to the House.

S.3203 — A bill to amend title 38, United States Code, to codify the requirements for appointment, qualifications, and pay for therapeutic medical physicists of the Department of Veterans Affairs, and for other purposes; Sponsor: Sen. Kaine, Tim [D-VA]; Committees: Senate - Veterans' Affairs

S.3210 — A bill to require the Secretary of Veterans Affairs, in consultation with the Secretary of Defense and the Secretary of Health and Human Services, to develop a clinical practice guideline or guidelines for the treatment of serious mental illness; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Veterans' Affairs

S.3216 — A bill to amend title XXVII of the Public Health Service Act to prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing cost-sharing requirements or treatment limitations with respect to diagnostic examinations for breast cancer that are less favorable than such requirements with respect to screening examinations for breast cancer; Sponsor: Sen. Blunt, Roy [R-MO]; Committees: Senate - Health, Education, Labor, and Pensions