



## Health Policy Briefing

March 5, 2018

### FDA Considers Efficacy of This Season's Flu Vaccine

Commissioner of Food and Drugs Scott Gottlieb issued a statement last week stating that public health experts must work to increase the effectiveness of the flu vaccine against H3N2 flu strain. His agency is working with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), and others within the federal government to determine why this year's vaccine has provided less than optimal protection against H3N2 -- the dominate strain in the current flu season. The agencies are seeking to understand how many were hospitalized for the flu, treated with antiviral medications for flu-like-illness, and whether those seniors who received a high-dose vaccine or adjuvanted flu vaccine had better outcomes than those who received a standard dose. The Food and Drug Administration (FDA) discussed the composition of next season's flu vaccines at an annual advisory committee meeting on March 1. The World Health Organization (WHO) has recommended changing two of the strains that are in this year's flu vaccine for the northern hemisphere. Gottlieb noted that flu season may continue to affect Americans into the month of April.

### Public Health Bills Pass House

The House of Representatives passed the following public health bills last week by voice vote unless other wise specified. H.R. 880, the Military Injury Surgical Systems Integrated Operationally Nationwide to achieve ZERO Preventable Deaths (MISSION ZERO) Act, establishes a grant program for military-civilian partnerships in trauma care. H.R. 767, the Stop, Observe, Ask, and Respond (SOAR) to Health and Wellness Act provides health care professionals training on how to identify and appropriately treat human trafficking victims. H.R. 1222, the Congenital Heart Futures Reauthorization Act, enhances research and surveillance on congenital heart disease and was passed by a vote of 394-7. H.R. 2410, the Sickle

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Cell Disease Research, Surveillance, Prevention, and Treatment Act, reauthorizes the Sickle Cell Disease Prevention and Treatment Demonstration Program. H.R. 2422, the Action for Dental Health Act, would reauthorize oral health promotion and disease prevention programs and grants to states to support oral health workforce activities and was passed by a vote of 387-13. Finally, H.Res. 443 recognizes the importance and effectiveness of trauma-informed care.

### ***WH, Congressional Leadership Talk Opioid Epidemic***

Officials from the Trump Administration met with leaders on Capitol Hill to discuss the steps taken to address the opioid epidemic since it was declared a public health emergency in October. The First Lady delivered opening remarks at the summit, followed by three administration panel discussions moderated by Kellyanne Conway. Secretary of the Department of Health and Human Services (HHS) Alex Azar, Department of Veterans Affairs (VA) Secretary David Shulkin, and Housing and Urban Development Secretary Ben Carson discussed prevention and treatment. Azar specifically expressed support for improving access to non-opioid pain therapies, while Carson discussed how communities can support those suffering from addiction through housing policy. Newly appointed acting director of the Office of National Drug Control Policy (ONDCP) Jim Carroll participated in a question and answer period about the Administration's efforts to control the crisis. Attorney General Jeff Sessions, Department of Homeland Security Kirstjen Nielson, and Deputy Secretary of State John Sullivan discussed law enforcement and interdiction. Sessions indicated that he plans to review with the Drug Enforcement Administration (DEA) whether changes are needed to current opioid production quotas. President Trump also made an appearance at the event, calling for stronger penalties for drug dealers. He noted that he is considering the possibility of suing opioid manufacturers. The President stated that the White House will release an opioid policy over the next three weeks. The Administration's emergency declaration was renewed in January and will expire on April 23.

During a separate event last week, FDA Commissioner Scott Gottlieb called for a national electronic prescribing platform and interoperable prescription drug management programs (PDMPs) to help combat the epidemic. According to Gottlieb, the agency is also considering whether it could use risk evaluation and mitigation strategies (REMS) to educate doctors about responsible prescribing.

In related news, the Government Accountability Office (GAO) announced plans to open an investigation into the White House's response to the opioid crisis. The investigation was requested by Senate Democrats. The GAO will review the actions taken by the administration to address the crisis since the president's emergency declaration last October.

### ***W&M Requests Information on Opioids***

The House Ways and Means Committee is requesting information from insurers, pharmacy benefit managers (PBMs), and health care providers and prescribers about how to better protect Medicare beneficiaries from opioid dependence and overdose. The Committee is currently drafting its own bipartisan opioid-related legislation, and is looking to leverage Medicare to combat opioid abuse and addiction. The lawmakers request feedback by March 15 related to overprescribing, data tracking, communication and education, and expanding treatment options in Medicare.

### ***FDA Looks to Speed Rare Disease Treatment Development***

Commissioner of Food and Drugs Scott Gottlieb announced steps his agency plans to take to expedited drug development for rare diseases. The announcement was made on the 11th annual rare disease day last week. The FDA is looking to simplify the form a drug company files for an orphan drug designation, and to establish an online tutorial to help companies navigate this process. The agency has also entered into a memorandum of understanding with the National Organization for Rare Disorders (NORD) to conduct outreach with FDA's staff.

### ***Legislators Release CARA 2.0***

A bipartisan group of eight senators released follow up legislation to the Comprehensive Addiction and Recovery Act (CARA), which was signed into law in 2016. The bill, dubbed “CARA 2.0,” would establish an initial three-day prescribing limit on opioids for acute pain. It would also strengthen services to promote recovery, such as an initiative aimed at young support services. The bill would require physicians and pharmacists to use their prescription drug monitoring program (PDMP) before prescribing or dispensing opioids. To increase the availability of treatment, CARA 2.0 would allow states to waive the number of patients a physician can treat with buprenorphine. It would increase penalties for opioid manufacturers who fail to report suspicious orders. The bill authorizes \$1 billion in additional funding, which includes \$10 million for a national education campaign, \$300 million to expand access to medication assisted treatment (MAT), \$200 million to build a national infrastructure for recovery support services, and \$300 million for expanding first responder training and access to naloxone. The two-year budget deal passed in February included \$6 billion for the opioid crisis for fiscal years 2018 and 2019. The bill is sponsored by Sens. Rob Portman (R-Ohio), Sheldon Whitehouse (D-R.I.), Amy Klobuchar (D-Minn.), Dan Sullivan (R-Alaska), Maggie Hassan (D-N.H.), Bill Cassidy (R-La.), Shelley Moore Capito (R-W.V.), and Maria Cantwell (D-Wash.).

### ***Sessions Announces Creation of New Opioid Task Force***

The Department of Justice (DoJ) has established a Prescription Interdiction and Litigation (PIL) Task Force to coordinate criminal and civil law enforcement efforts related to opioids and strengthen the Department’s response to the diversion and over-prescribing of pain medication. The Task Force will focus on targeting manufacturers and distributors, including pharmacies, pain management clinics, drug testing facilities, and individual physicians, that could be contributing to the opioid abuse epidemic. It will ensure that companies are following FDA regulations for marketing, and evaluate whether changes are needed to the current distribution system. It will also examine lawsuits brought forth by state and local governments.

### ***HELP Advances Four Public Health Bills***

The Senate Health, Education, Labor, and Pensions (HELP) Committee has favorably reported four pieces of public health legislation to the full Senate, including:

- S.2434, Animal Drug and Animal Generic Drug User Fee Amendments of 2018, which would reauthorize user fee programs relating to new animal drugs and generic new animal drugs;
- S. 292, Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act, to maximize discovery and accelerate the development and availability of promising childhood cancer treatments;
- S.2278, State Offices of Rural Health Reauthorization Act of 2018, which would provide grants to improve health care in rural areas; and
- S.1091, Supporting Grandparents Raising Grandchildren Act, which would establish a federal task force to support grandparents raising grandchildren.

### ***Labor-HHS Could Face Cuts as a Result of CHIMPS Debate***

The fiscal year (FY) 2018 Labor-Health and Human Services appropriations bill could face \$5 billion in cuts as House and Senate Republicans negotiate a spending bill to keep the government open beyond March 23, when the current continuing resolution (CR) expires. Appropriators are currently debating whether or not to limit an accounting gimmick known as CHIMPS (Changes in Mandatory Program Spending) to \$19 billion that could be used to pay for spending elsewhere. Some republicans support capping CHIMPS at \$14 billion.

## ***Members Named to Budget/Appropriations Reform Committee***

Sixteen lawmakers (full list below) have been appointed to serve on the Joint Select Committee on Budget and Appropriations Process Reform. The committee was created by the latest bipartisan budget deal (H.R. 1892) and are tasked with providing recommendations to reform the budget and appropriations process. The group will be led by Budget Chairman Steve Womack (R-Ark.) and Appropriations Committee Ranking Member Nita Lowey (D-N.Y.). The committee will convene at least five public meetings and three public hearings before November 30, when they will offer a report and legislative language approved by a bipartisan majority to both chambers of Congress.

### **House Speaker Paul Ryan's Appointments**

- Rep. Steve Womack (R-AR-03) – Co-Chair -- Budget Chair, appropriations
- Rep. Pete Sessions (R-TX-32) -- Rules Chair
- Rep. Rob Woodall (R-GA-07) – Budget
- Rep. Jodey Arrington (R-TX-19) – Budget

### **House Minority Leader Nancy Pelosi's Appointments**

- Rep. Nita Lowey (D-NY-17) – Co-chair – Appropriations Ranking Member
- Rep. John Yarmuth (D-KY-03) – Budget Ranking Member
- Rep. Lucille Roybal-Allard (D-CA-40) – Homeland Security Approps Ranking Member
- Rep. Derek Kilmer (D-WA-06) – Appropriations Vice Ranking Member

### **Senate Majority Leader Mitch McConnell Appointments**

- Sen. Roy Blunt (R-MO) – Appropriations
- Sen. David Perdue (R-GA) – Budget
- Sen. James Lankford (R-OK) – Appropriations
- Sen. Joni Ernst (R-IA)

### **Senate Minority Leader Chuck Schumer's Appointments**

- Sen. Sheldon Whitehouse (D-RI) – Budget
- Sen. Brian Schatz (D-HI) – Appropriations
- Sen. Michael Bennet (D-CO)
- Sen. Mazie Hirono (D-HI)

## ***PACCARB Urges HHS to Protect AMR Funding, Codify Council***

The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) has agreed to send two letters to Secretary of Health and Human Services Alex Azar outlining the Council's concerns about funding for combating antimicrobial resistance in veterinary and human medicine, and to request that PACCARB be codified into law. PACCARB **requests** that funding be maintained or increased for the CDC Antibiotic Resistance Solutions Initiative, the Agency for Healthcare Research and Quality (AHRQ), and the National Institute of Food and Agriculture at the U.S. Department of Agriculture. The council members also **recommend** that PACCARB, originally established through an Executive Order, be codified into law so it can continue its mission to address antibiotic-resistant bacterial infections in humans and animals. PACCARB's next public meeting is scheduled for May 16.

## Upcoming Congressional Meetings and Markups

*House Energy and Commerce Oversight and Investigations Subcommittee hearing “Examining U.S. Public Health Preparedness and Response Efforts to Seasonal Influenza;” 10:00 a.m., 2123 Rayburn Bldg.; March 8*

*Senate Health, Education, Labor and Pensions Committee hearing on “The Opioid Crisis: Leadership and Innovation in the States;” 10:00 a.m., 430 Dirksen Senate Office Building; March 8*

*House Veterans’ Affairs Subcommittee on Health field hearing “VA Healthcare: Maximizing Resources in Puerto Rico;” 10:00 a.m., San Juan, PR; March 12*

*House Veterans’ Affairs Subcommittee on Health hearing “FY 2019 Department of Veterans Affairs Budget Request for the Veterans Health Administration;” 10:00 a.m., 334 Cannon Bldg.; March 15*

## Recently Introduced Health Legislation

*H.R.5080 (introduced by Rep. George Holding): To amend title XVIII to provide for coverage under the Medicare program of opioid treatment program services; Energy and Commerce, Ways and Means*

*H.R.5083 (introduced by Rep. Richard E. Neal): To amend title XVIII of the Social Security Act to provide for coverage of certain services furnished by opioid treatment programs under the Medicare program; Energy and Commerce, Ways and Means*

*H.R.5092 (introduced by Rep. Rosa L. DeLauro): To conduct or support further comprehensive research for the creation of a universal influenza vaccine; Energy and Commerce*

*H.R.5095 (introduced by Rep. Robert E. Latta): To amend the Veterans Access, Choice, and Accountability Act of 2014 to improve access of veterans to cancer treatment at non-Department of Veterans Affairs facilities, and for other purposes; Veterans’ Affairs*

*H.R.5097 (introduced by Rep. Tom Rice): To amend title 38 and title 5, United States Code, to require the Secretary of Veterans Affairs and other officials of the Department of Veterans Affairs to receive health care from the Department, and for other purposes; Veterans’ Affairs*

*S.2451 (introduced by Sen. Bill Cassidy): A bill to require the Secretary of Health and Human Services to consider State analysis and sharing of prescription drug monitoring program data in determining prescription drug monitoring program grants to States; Health, Education, Labor, and Pensions*

*H.Res.752 (introduced by Rep. Christopher H. Smith): Recognizing the rise of cardiovascular disease as the world’s leading cause of preventable death and disability and as the global public health crisis of our generation and recognizing February 2018 as “American Heart Month”; Energy and Commerce*

*H.Res.757 (introduced by Rep. Hank Johnson, Jr.): Expressing support for the designation of October 17 as “National Vitiligo Awareness Day”; Energy and Commerce*

*H.R.5100 (introduced by Rep. Stephen Knight): To amend the Public Health Service Act to authorize grants to States to establish and operate recovery home certification programs, and for other purposes; Energy and Commerce, Judiciary*

*H.R.5102 (introduced by Rep. Katherine M. Clark): To amend the Public Health Service Act to authorize a loan repayment program for substance use disorder treatment employees, and for other purposes; Energy and Commerce*

*H.R.5104 (introduced by Rep. Kurt Schrader): To amend title XVIII of the Social Security Act to provide for a special enrollment period under Medicare for individuals enrolled in COBRA continuation coverage, and for other purposes; Energy and Commerce, Ways and Means, Education and the Workforce*

*H.R.5109 (introduced by Rep. Ann M. Kuster): To amend the 21st Century Cures Act to ensure the equitable distribution of resources to address the opioid epidemic, and for other purposes; Energy and Commerce*

*H.R.5115 (introduced by Rep. Andre Carson): To expand and improve the programs and activities of the Department of Health and Human Services for awareness, education, research, surveillance, diagnosis, and treatment concerning rare diseases and conditions; Energy and Commerce*

*H.R.5124 (introduced by Rep. Betty McCollum): To require the Secretary of Health and Human Services to establish a community action opioid response grant program; Education and the Workforce*

*S.2453: A bill to amend title XVIII of the Social Security Act to require hospitals to provide the Secretary with information on the hospital's acquisition costs for 340B drugs and the total revenues received by the hospital for such drugs; Finance*

*S.2456: A bill to reauthorize and expand the Comprehensive Addiction and Recovery Act of 2016; Health, Education, Labor, and Pensions*

*S.2460: A bill to amend title XVIII of the Social Security Act to require e-prescribing for coverage under part D of the Medicare program of prescription drugs that are controlled substances; Finance*

*S.2465 (introduced by Sen. Tim Scott): A bill to amend the Public Health Service Act to reauthorize a sickle cell disease prevention and treatment demonstration program and to provide for sickle cell disease research, surveillance, prevention, and treatment; Health, Education, Labor, and Pensions*

*S.2469 (introduced by Sen. Sherrod Brown): A bill to amend the Public Health Service Act to enhance efforts to address antibiotic resistance, and for other purposes; Health, Education, Labor, and Pensions*

*S.2473 (introduced by Sen. Bill Cassidy): A bill to amend title 38, United States Code, to require the Secretary of Veterans Affairs to furnish organ transplant care to veterans at non-Department of Veterans Affairs facilities, and for other purposes; Veterans' Affairs*

*S.2476 (introduced by Sen. Tina Smith): A bill to amend the Federal Food, Drug, and Cosmetic Act to ensure that valid generic drugs may enter the market; Health, Education, Labor, and Pensions*

*H.Res.760 (introduced by Rep. Donald M. Payne, Jr.): Supporting the designation of March 2018 as National Colorectal Cancer Awareness Month; Oversight and Government Reform*

*H.R.5138 (introduced by Rep. Mike Kelly): To amend the Internal Revenue Code of 1986 to improve access to health care through modernized health savings accounts; Ways and Means*

*H.R.5140 (introduced by Rep. Markwayne Mullin): To make improvements to the Account For the State Response to the Opioid Abuse Crisis to improve tribal health; Energy and Commerce*

*H.R.5150 (introduced by Rep. Sander M. Levin): To amend title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation; Energy and Commerce, Ways and Means*

*H.R.5151 (introduced by Rep. Ben Ray Lujan): To amend the Public Health Service Act to reauthorize a grant program improving treatment for pregnant and postpartum women; Energy and Commerce*

*H.R.5152 (introduced by Rep. Richard M. Nolan): To direct the Secretary of Veterans Affairs to establish a grant program for eligible nonprofit organizations to carry out positive psychology reconditioning programs for veterans; Veterans' Affairs*

*S.Res.423 (introduced by Sen. Sherrod Brown): A resolution designating February 28, 2018, as “Rare Disease Day”; submitted, considered, and agreed to by voice vote*

*S.2478 (introduced by Sen. Claire McCaskill): A bill to amend the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs; Finance*

*S.2481 (introduced by Sen. John Kennedy): A bill to increase the penalties for fentanyl trafficking; Judiciary*