



Health Policy Briefing

January 18, 2016

President Delivers Seventh and Final State of the Union Address

On Tuesday, 44th President of the United States Barack Obama delivered his seventh and final State of the Union address. During the speech, the President focused on the progress made during his tenure in office and his vision for the future of the country. He focused on his economic record – 70 straight months of private-sector job growth, lower unemployment, and the shrinking deficit – as well as overcoming the nation’s partisan divide. He specifically highlighted reducing prescription drug and heroin abuse as one issue on which he wants to work with Congress. Perhaps most notable was the President’s commitment to finding a cure for cancer once and for all. Obama announced that Vice President Joe Biden will lead this effort. Accelerating a cure for cancer has been a focus of the Vice President since he lost his oldest son to brain cancer last year. South Carolina Governor Nikki Haley delivered the official GOP response to the State of the Union, focusing largely on the national security and the President’s foreign policy. Rep. Mario Diaz-Balart (R-Fla.) delivered a response in Spanish, and Rep. Wayne Allyn Root (R-Nev.) delivered a response on behalf of the Tea Party. Following the President’s address, Republicans departed for Baltimore for the party’s annual policy retreat to discuss their platform for the 2016 Presidential election year.

Republicans Hold Annual Policy Retreat

Last week, the Congressional Republicans held their annual policy retreat to develop a policy agenda for the coming year. During the retreat, Speaker of the House Paul Ryan (R-Wis.) announced a five-point plan to promote his party in the time leading up to the 2016 elections: address national security, restore economic growth, rethink health care, overhaul poverty programs and restore the constitution. Republican leadership stressed that much of the responsibility for further developing the agenda would be in the hands of committee chairmen and rank and file membership.

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Both Speaker Ryan and Senate Majority Leader Mitch McConnell (R-Ky.) committed to trying to pass all 12 individual spending bills this year, despite reservations from those members of the party that would rather not vote on a budget during an election year. Both leaders have agreed on an open amendment process. Meanwhile, Senate Republicans held a meeting last week to consider potential changes to the filibuster. The specific changes being proposed are to eliminate the filibuster on motions to consider bills on the Senate floor, to reduce the amount of time that must elapse before a vote is held to begin floor debate, and to lessen the time to proceed to a final vote after members have already voted to end dilatory debate. Senate rules currently require 30 hours of debate to occur between a cloture vote and a final vote. These changes would require the support of two-thirds of the chamber, and Democrats have been tentatively receptive to the ideas. If approved, the changes would take effect at the beginning of next year.

Moonshot to Cure Cancer Kicks Off

Almost immediately following the President's State of the Union challenge to the nation to find a cure for cancer, Vice President Biden began work on the effort. The Vice President has said that his priority will be increasing both public and private dollars to fight cancer, and on breaking down the silos that prevent the sharing of cancer data and research. Biden has said that he will convene the first meetings with administration officials next month, and that he will continue meetings with leaders in cancer research and advocacy. During a roundtable discussion with medical researchers at the University of Pennsylvania on Friday, he explained that the President will soon announce a presidential memorandum that allows Biden to convene a task force on the subject. He also noted that this is an issue that he plans on being involved in for the rest of his life. The Vice President's efforts have been praised by House Energy and Commerce Committee Chairman Fred Upton (R-Mich.), who has pushed for increased funding for medical research through H.R. 6, the 21st Century Cures Act. Immediately prior to the State of the Union address, a group of biotech companies, pharmaceutical manufacturers, doctors and researchers announced the launch of a coalition called the Cancer MoonShot 2020. The Vice President's son-in-law, a medical doctor, spoke at the Coalition's launch event. The group aims to complete immunotherapy clinical trials for up to 20 tumor types in as many as 20,000 patients by the year 2020.

House Passes Child Nicotine Poisoning Prevention Act

The House of Representatives has passed legislation to protect children from exposure to e-liquids containing nicotine. The Child Nicotine Poisoning Prevention Act (S. 142/H.R. 3242) will ensure child-resistant packaging for these products, which are used in e-cigarettes and other e-smoking applications. Packaging in line with the Consumer Product Safety Commission's child-resistant standards would be required 180 days after enactment of the bill. The House version of the bipartisan bill was introduced by Energy and Commerce Committee members Susan Brooks (R-Ind.) and Elizabeth Esty (D-Conn.). E-liquids are often colorful and come in many flavors that could appeal to children. The Centers for Disease Control and Prevention (CDC) have found a significant increase in the number of calls to poison control centers involving the liquid nicotine used for e-cigarettes, with more than half the calls involving children under the age of five. S. 142, introduced by Sen. Bill Nelson (D-Fla.), was cleared by the Senate last month. The House passed H.R. 3242 by voice vote, and the bill will be sent to the President for his signature.

USPSTF Finalizes Breast Cancer Screening Recommendations

The U.S. Preventive Services Task Force (USPSTF) has finalized its controversial recommendations on mammography screenings for breast cancer. The Affordable Care Act (ACA) mandates private insurance coverage without copays for services that receive a USPSTF grade of "A" or "B." The federal task force assigned routine mammographies for women in their 40s a "C" rating. The rating is a result of weighing the risks of over diagnosis and unnecessary treatment against the potential benefit of routine screenings for younger women.

West Africa Declared Ebola Free

The World Health Organization (WHO) has declared the end of Ebola in West Africa. Guinea, Liberia, and Sierra Leone, the three countries hit hardest by the two-year epidemic, no longer have any known cases of the disease. Officials, however, are not ruling out the possibility of more cases being recorded in the region and have urged countries to continue surveillance. Over 28,000 people have been infected with the highly contagious Ebola since August 2014, and more than 11,000 have died. WHO will decrease its staff presence in the area from 1,200 people to 600 people by the end of the year.

FDA News

HELP Advances Califf's FDA Nomination

Dr. Robert Califf, the White House's nominee to lead the Food and Drug Administration (FDA), was approved by the Senate Health, Education, Labor and Pensions (HELP) Committee last week by voice vote. Dr. Califf is currently the FDA's deputy commissioner for medical products and tobacco. He is a cardiologist and a longtime researcher at Duke University. He received statements in support of his nomination from Committee Chairman Lamar Alexander (R-Tenn.) and Ranking Member Patty Murray (D-Wash.) at the start of the executive session. Presidential candidate Bernie Sanders (I-Vt.) was absent from the vote on Tuesday, but expressed his opposition to the nomination in a statement, reiterating concerns he had first voiced during Califf's confirmation hearing in November. He cites Dr. Califf's ties to the drug industry and has criticized Califf's opposition to the importation of drugs from Canada as a means to lower costs. Sen. Sheldon Whitehouse (D-R.I.) also spoke about the need to deal with the price hikes by drug companies producing pharmaceuticals to treat rare diseases. Before his nomination is voted on by the full Senate, Sen. Lisa Murkowski (R-Alaska) wants the agency to address her concerns regarding genetically-engineered salmon. Chairman Alexander expressed hopes that these conversations would be quick. During the executive session, Chairman Alexander also stated his continued commitment to introducing a medical innovation bill to parallel the House's 21st Century Cures, but no timeline was offered.

HELP Releases Report on Monitoring of Medical Device Safety

Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee Patty Murray (D-Wash.) has released a report titled "**Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients.**" The report includes the results of HELP's Democratic staff investigation into the bacterial infection outbreak in Seattle stemming from medical devices known as duodenoscopes, used to diagnose and treat conditions of the pancreas and bile duct. The manufacturer of the device, Olympus, knew by early 2013 that bacteria could spread even after cleaning the duodenoscope according to specifications. The outbreak was discovered in September of 2013, but the Food and Drug Administration (FDA) did not begin alerting hospitals and the public until February 2015. A total of 250 people in 10 states and four countries became ill as a result of these particular duodenoscopes. The report concludes that the outbreak was able to spread nationwide because hospitals and federal regulators failed to take timely action. Outdated adverse event databases and untimely and incomplete manufacturer and hospital self-reporting are blamed for the FDA's misunderstanding of the severity of the outbreaks. The report recommends that Congress fund a medical device monitoring system, and that the FDA implement a way to more quickly communicate information about adverse events.

GAO Report: FDA Struggles to Track Safety of Expedited Drugs

The Government Accountability Office (GAO) has found that the Food and Drug Administration (FDA) lacks reliable, readily accessible data on tracked safety issues and postmarket studies needed to meet postmarket safety reporting requirements and conduct systematic oversight of drugs approved through expedited pathways. From October 2006 through the end of 2014, the FDA granted 525 fast-track requests. But the agency struggles to track the safety of these drugs once they are on the market, according to the report. These problems have prevented the FDA from publishing statutorily required reports on potential safety issues and postmarket studies in a timely manner. GAO recommends that the FDA develop plans that comprehensively outline how to correct the problems with postmarket safety data.

Upcoming Congressional Meetings and Hearings

Senate Special Aging Committee: Field Hearing - Fighting Against a Growing Epidemic: Reducing the Misuse and Abuse of Opioids in America; 9:45 a.m., Governor's Office Building, 200 Madison Street, Jefferson City, MO 65101 Ballroom; January 19

House Minority Whip Steny Hoyer, D-Md., hosts a roundtable discussion on the Affordable Care Act's "current open enrollment period, availability of financial assistance, and outreach efforts to encourage Prince George's County residents to sign up for affordable health coverage in 2016 before the January 31 deadline;" 1:30 p.m., 800 J Shoppers Way, Largo, Md.; January 19

Senate Health, Education, Labor and Pensions Committee: hearing titled "Improving the Federal Response to Challenges in Mental Health Care in America;" 10:00 a.m., 430 Dirksen Bldg.; January 20

Senate Finance Committee: hearing titled "CO-OPs: A Review of the Financial and Oversight Controls;" 9:30 a.m., 219 Dirksen Bldg.; January 21

House Veterans' Affairs Health Subcommittee: hearing on "Choice Consolidation: Evaluating Eligibility Requirements for Care in the Community;" 10:00 a.m., 334 Cannon Bldg.; February 2

House Veterans' Affairs Health Subcommittee: hearing on "Choice Consolidation: Improving VA Community Care Billing and Reimbursement;" 10:00 a.m., 334 Cannon Bldg.; February 11

Health Legislation Recently Introduced

H.R.4362 (introduced by Rep. Todd Rokita): To amend the Social Security Act to replace the Medicaid program and the Children's Health Insurance program with a block grant to the States, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and the Workforce, the Judiciary, Natural Resources, House Administration, Rules, and Appropriations, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; January 11

H.R. 4365 (introduced by Rep. Hudson):. A bill to amend the Controlled Substances Act with regard to the provision of emergency medical services; to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; January 12

H.R. 4367 (introduced by Rep. Pitts): A bill to amend title XIX of the Social Security Act to end the increased Federal funding for Medicaid expansion with respect to inmates; to the Committee on Energy and Commerce; January 12

H.R. 4368 (introduced by Rep. Pitts): A bill to amend title XIX of the Social Security Act to clarify the treatment of lottery winnings and other lump sum income for purposes of income eligibility under the Medicaid program, and for other purposes; to the Committee on Energy and Commerce; January 12

H.R. 4374 (introduced by Rep. Schakowsky): A bill to amend the Public Health Service Act to improve mental and behavioral health services on college and university campuses; to the Committee on Energy and Commerce, and in addition to the Committee on Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; January 12

H.R. 4378 (introduced by Rep. Cartwright): A bill to amend the Public Health Service Act to provide grants for treatment of heroin, opioids, cocaine, methamphetamine, 3,4-methylenedioxymethamphetamine (ecstasy), and phencyclidine (PCP) abuse, and for other purposes; to the Committee on Energy and Commerce; January 13

H.R. 4388 (introduced by Rep. Loeb sack): A bill to amend the Public Health Service Act to authorize a primary and behavioral health care integration grant program; to the Committee on Energy and Commerce; January 13

H. Res. 586 (introduced by Rep. Knight): A resolution expressing support for designation of the fourth week in May as "DIPG Awareness Week" to raise awareness and encourage the research into cures for diffuse intrinsic pontine glioma (DIPG) and pediatric cancers in general; to the Committee on Energy and Commerce; January 13

S. 2438 (introduced by Sen. Brown): A bill to amend titles XI and XIX of the Social Security Act to establish a comprehensive and nationwide system to evaluate the quality of care provided to beneficiaries of Medicaid and the Children's Health Insurance Program and to provide incentives for voluntary quality improvement; to the Committee on Finance; January 12

S. 2443 (introduced by Sen. Baldwin): A bill to support the establishment of a Standards Coordinating Body in Regenerative Medicine and Advanced Therapies; to the Committee on Health, Education, Labor, and Pensions; January 12