

## **Overview**

In the first three weeks of his administration, President Trump has already signed 22 executive orders. While that number seems steep, President Obama signed 19 orders in his first 12 days while Trump signed 18 in that same timeframe. The public response to many of these executive orders, such as blocking U.S. entry from 7 Muslim-majority countries and a commitment to speed-up infrastructure projects like the Keystone XL and Dakota Access Pipelines, has resulted in continued demonstrations across the country and several lawsuits against the administration questioning the constitutionality of some of the orders. Despite all this attention focused on the president, significant activity is happening in Congress. This month, more confirmations of political appointees are expected and several bills are scheduled to move out of committee on issues ranging from drug pricing to Obamacare repeal.

## **Budget and Appropriations**

The Trump administration has sent mixed signals about releasing a budget, but most recently said it will release a skinny budget by March and full budget by late April. Although the president was supposed to deliver his fiscal blueprint to Congress by the beginning of February, virtually all newly elected presidents miss that first-Monday-in-February deadline. Trump has indicated he wants to increase funding for the Department of Defense, the wall on the southern border and an infrastructure bill but also cut taxes and replace Obamacare so having the budget spell out these details will be key in shaping what legislation Congress sends to his desk for signature.

### Line-Item Appropriations

Leading House Republicans are moving forward with their controversial push to bring back a weak version of earmarks, rebranded "line-item appropriations." It is unlikely naming specific recipients as with earmarks will return this Congress, but the House is determined to open the door to regaining the ability to direct spending with more precision. We should hear more about line-item appropriations when the Rules Committee kicks off hearings on the topic in the next few weeks. Tom Cole (R-OK), Rules Committee Vice Chairman, is developing his strategy to end the six-year ban on earmarks. Cole and other appropriators plan to make their case for re-instituting line-item appropriations by promising to revamp the process and acknowledging the kinds of "abuses" that led to jail time for some members. They hope to gain traction by the start of the FY 2018 appropriations process. He stressed that the House would comply with old earmark rules, such as attaching the member's name to the money and forcing it go through the regular appropriations process. G2G was on the hill last week and talked with several staffers about this proposal and have yet to hear confirmation that this will gain traction, but we will follow this closely.

### Debt-to-GDP Ratio-Based Budget Proposal

House Budget Committee Vice Chairman Todd Rokita (R-IN) proposed that the FY 2018 budget does not balance within 10 years, but rather, it follow a debt-to-GDP ratio as the target. Rokita is looking to reduce the debt-to-GDP ratio to 60-65% in order to stabilize it. The proposal would require \$4 trillion in cuts over 10 years rather than the \$7.5 trillion called for to reach a balance. Rokita's plan would avoid a fight with the Trump administration over cuts to Medicare, and would allow an infrastructure package to count towards reaching the goal. Rokita would have to sell his plan to the House Republican Conference, and conservatives are skeptical. The Heritage Foundation is promoting an alternative proposal that includes \$10.5 trillion in cuts.

## **Executive Orders and Regulations**

### Rescinding Regulations

One of President Trump's executive orders requires for every new federal regulation implemented, two must be rescinded. The freeze also includes a delay of 60 days or more in the effective date of regulations the Obama administration managed to get out the door in recent months, but which have not yet taken effect. House Speaker Paul Ryan (R-WI) and many other Republicans applauded the order. As a result of this order, as of January 31st, a total of 62 items that were due to be published in the coming days were listed as withdrawn at the agencies' request. However, the total number of notices pulled from the process seems to be substantially higher. The administration's order does allow for exceptions for "emergency situations or other urgent circumstances relating to health, safety, financial, or national security matters, or otherwise." However, this is unclear so many agencies are pulling everything pending at the Federal Register. Public Citizen, the Natural Resources Defense Council and the Communications Workers of America have filed a lawsuit against the Executive Order. The groups argue that Trump exceeded his constitutional authority with the directive, and that he violated the Administrative Procedure Act by instructing agencies to act arbitrarily in canceling regulations.

### Federal Employee Hiring Freeze

Additional White House executive orders and memos call for both the hiring of 15,000 immigration and border patrol federal employees and the freezing of any new hiring of federal workers. The hiring freeze explicitly states, "No vacant positions existing at noon on January 22, 2017, may be filled and no new positions may be created, except in limited circumstances." Military personnel are exempted and heads of agencies may decide a position is necessary to meet national security or public safety concerns. The White House didn't say whether FDA jobs funded by industry user fees would be exempt from the freeze. These details are particularly important for FDA, whose drug center had more than 700 vacancies at the end of last year. The recent 21st Century Cures Act included provisions to help FDA speed up hiring and attract new talent to expedite drug approvals. Despite this confusion, the White House said it's up to the agencies to sort out such details.

### **Defense**

Secretary of Defense Mattis has ordered Deputy Defense Secretary Bob Work, an appointee from the Obama administration, to review the current fiscal year budget in order to draft a supplemental spending proposal as well as a new budget request for FY 2018. The supplemental request will result in a higher topline, according to Mattis, adding that some "lower-priority programs" could be cut. According to the House Armed Services Committee Chairman Mac Thornberry (R-TX), the Trump administration's request for an emergency supplemental should start at \$18 billion for the Pentagon. The \$18 billion starting point includes the Boeing Super Hornet aircraft and Lockheed Martin F-35 Joint Strike Fighters. The House version of the 2017 defense authorization bill included that funding, but it was left out in conference with the Senate for the final bill. Mattis' supplemental budget is due at the Office of Management and Budget (OMB) by March 1, with the full FY 2018 budget proposal due by May 1. The Trump Administration will have to prioritize either improving readiness and modernization or increasing the number of troops (especially within the Navy), both of which Trump has listed as his main goals. In addition, under Trump's direction the U.S. Army plans to spend \$300 million to add 6,000 recruits to reach its new recruitment goal of 68,500 for the remainder of this fiscal year, which would be the biggest addition since it began in 1973. The total target number is 476,000 active-duty soldiers.

### **Health**

#### Obamacare and Medicaid

House Speaker Ryan (R-WI) is giving Republicans until the end of the year to come up with and pass an Obamacare replacement, although House Ways and Means Chairman Kevin Brady (R-TX) aims to have his committee pass a bill by March. This is just one of several committees that will need to markup the

Obamacare replacement bill so it will take several months and into 2018 for a substantive bill to materialize. Republicans must also tackle the individual insurance market, which they pledge to do quickly. Some are also pushing to overhaul Medicaid by converting into a block grant system that gives states fixed sums to spend on their respective programs. With 31 states expanding Medicaid as of January 2017, many governors on both sides of the aisle are asking Congress to move carefully with such reforms. For example, in Ohio alone, Medicaid expansion benefited 700,000 residents, brought the state's uninsured rate to record lows and provided necessary treatment for those with substance abuse and mental health issues, according to Governor Kasich, who has led efforts to maintain Medicaid expansion funding. All of this impacts any legislation to repeal Obamacare. To simplify this process and accelerate action, multiple lawmakers are suggesting using a combination of administrative actions and smaller bills to create piecemeal fixes over time.

### FDA

The FDA is pushing back against the Second Circuit's *Caronia* decision, which said the agency cannot prohibit or criminalize truthful off-label promotions, in a recently released memo on First Amendment considerations for drug and device promotions. The memo rejects all the alternatives proposed by the Second Circuit that include the government prohibiting certain off-label uses altogether, requiring specific disclaimers for off-label promotion, or capping physician prescriptions for off-label uses. FDA argues that prohibiting all off-label use would impose more restrictions on speech. The FDA also argues that its authority over drug and device promotion prevents public harm, protects against fraud, misrepresentation and bias; and makes sure that health care resources aren't diverted toward ineffective treatments. In fact, a review of 16,500 drugs marketed before the 1962 law found that 70% of their claimed uses were not supported by substantial evidence. Of the thousands of drugs reviewed, only 434 were found to be effective for all their claimed uses.

### FDA Oncology Center

House Energy and Commerce Committee Chairman Greg Walden (R-OR) and Ranking Member Frank Pallone, Jr. (D-NJ) recently welcomed the FDA's establishment of an Oncology Center of Excellence. The announcement, part of Vice President Biden's Cancer Moonshot Initiative, is the culmination of the FDA's June 2016 announcement to create the first-of-its-kind center.

### FDA Human Subject Protection

The first-ever revision to the human subject protection regulations known as the Common Rule will affect nearly 20 federal agencies, academic centers and teaching hospitals that spend billions of federal research dollars. The final rule dropped many proposed provisions, including the most controversial one to reclassify all biospecimens as human subjects—whether or not they can be identified—with limited ability to waive consent requirements. The final rule also nixed a proposal that all clinical trials would be subject to the regulations, regardless of whether federal dollars paid for the study. The final rule moved forward with the proposal to require a single institutional review board to oversee a study being conducted at multiple sites, with three years to comply with this rule. IRB approval is required before a researcher can enroll participants in a covered study. The changes will also affect drug and device companies as the FDA has agreed to revise its human subject rules in concert with the Common Rule update.

### Biosimilars

The FDA released draft guidance that allows for an "interchangeable" designation with biosimilars and their reference products. Pharmacists are now able to substitute a drug with its biosimilar without a physician's authorization as long as that biosimilar is deemed interchangeable. The draft guidance sets

out the types of evidence, including results of “switching” studies, and that biosimilar applicants would have to prove interchangeability. Additionally, the FDA released a final guidance on the naming of biosimilars. Under the guidance, biologics and biosimilars can have nonproprietary names that share a core drug substance name and an FDA-designated suffix composed of four lowercase letters that is unique for each product. An applicant can submit up to 10 proposed suffixes. The FDA said its plan would prevent inadvertent substitution and support safety monitoring of biological products after they are on the market.

### eHealth

The annual HIMSS conference is on February 19-23. HIMSS is traditionally an opportunity for HHS, CMS and ONC to enlighten the health IT world about their work, which is of great interest this year with implementation of payment reform and the 21st Century Cures Act on the docket. Telemedicine expansion and the EHR incentive program, meaningful use, are also hot ticket items. Secretary of Health and Human Services (HHS) Secretary Tom Price was just sworn in late last week so his work on health IT issues has just begun. Some insiders expect HHS will cancel the expanded electronic health record oversight program that ONC released last fall, and may cancel Stage 3 of meaningful use. Finally, ONC's direction and very existence could come into question under Secretary Price.

### Drug Prices

President Trump says drug prices are “astronomical” and something needs to be done. He planned a meeting with leading pharmaceutical companies’ CEOs last week. The pharmaceutical giants propose not lowering list prices, but rather refunding some of the money to insurers if a drug doesn’t work as expected. The concept of pay-for-performance isn’t new in the industry. The number of such agreements between drug-makers and insurers has grown in the past year as the industry seeks to defuse criticism over the soaring prices of some brand drugs, which can cost \$10,000 a month or more for cancer treatments. The drug industry strongly opposes forcing companies to bid for government business. Meanwhile, lawmakers are pushing various ideas of their own to combat high prescription drug prices. Solutions include allowing Medicare to negotiate with pharmaceutical manufacturers to lower prices, increasing access to generic drugs and importing less expensive drugs from other countries. Senators Susan Collins (R-ME) and Claire McCaskill (D-MO) last week reintroduced the Increasing Competition in Pharmaceuticals Act, which would expedite the FDA’s review of certain generic drug applications. Representatives Gus Bilirakis (R-FL) and Kurt Schrader (D-OR) introduced a bill, the Lower Drug Costs Through Competition Act, intended to increase generic drug development and lower the costs of pharmaceuticals. House Energy and Commerce Committee Chairman Greg Walden (R-OR) said that his committee will consider legislation this week or next.

### Veterans Choice

Senate Armed Services Committee Chairman John McCain (R-AZ) is working to expand the Veterans Choice Program. He sent a letter to David Shulkin, who is the nominee for Secretary of the Department of Veterans Affairs (VA) and the current Undersecretary, asking for his position on the future of the Veterans Choice Program, which is set to expire in August 2017. The Veterans Choice Program allows eligible veterans receiving VA healthcare benefits to use those benefits at an approved health facility near them, allowing the veteran to choose their physician and receive care in a convenient location. It also helps ease the burden of overfilling waiting rooms and the backlog of cases facing the VAMCs.

### **Economic Development**

#### Bipartisan Coalition

In an effort to bring some bipartisanship to an otherwise divided House, dozens of centrist House Republicans and Democrats are coming together as potential allies in the looming tax and infrastructure discussions. Pro-business House Democrats who call themselves the "New Democrat Coalition" and a group of Republican moderates gathered in early February in a Capitol Hill basement room to talk about joining forces and potentially combining their vote clout. With 54 New Dems and 54 moderate Republican members, the 108-member group has a good deal of power in the context of a 435-seat House chamber.

### Dodd Frank Act

Following the Dodd-Frank directive Trump signed the first week of February, Republicans in Congress under the leadership of House Financial Services Chairman Jeb Hensarling (R-TX) are moving forward to undo the 2010 law. Meanwhile House Minority Leader Nancy Pelosi (D-CA) calls this effort a "Wall Street First" agenda. Hensarling's 2016 bill that will be updated and introduced later this month is called the Financial Choice Act, which would eliminate the Volcker Rule's ban on certain investments, the Financial Stability Oversight Council's ability to label firms that pose risks to the wider financial system, and regulators' ability to intervene when banks fail. Also, Senator Sherrod Brown (D-OH), the top Democrat on the committee in the other chamber said he is eager to work on a bipartisan bill, but not if it entails ripping up core parts of the law that protect consumers. Senate Republicans do need at least eight Democrats to join them on a bipartisan Dodd-Frank overhaul. But it is a challenge because while 10 Senate Democrats facing re-election in states Trump won should be open to negotiation, loosening restrictions on banking that could harm consumers runs contrary to the Democratic party's platform.

### **Education**

Early last week, Betsy DeVos was confirmed as Secretary of Education in a rare tie-breaking vote. Republicans in Congress are moving ahead on plans to erase some of the Education Department regulations finalized during the Obama administration. House Republicans have filed Congressional Review Act (CRA) resolutions to stop the Obama administration's teacher preparation regulations and its accountability rule under the Every Student Succeeds Act, which was enacted two years ago. Other education regulations that could be on the chopping block under the CRA include the borrower defense-to-repayment rules and a set of regulations governing state oversight of colleges and universities. If the CRA resolutions pass in coming weeks, the regulations would be blocked and the department, under the law, would also be prohibited from writing new, similar rules unless Congress grants them power to do so.

### **Agriculture**

The Senate Agriculture Committee this month is expected to take up the nomination of former Georgia Governor Sonny Perdue to serve as Agriculture secretary, though a date for a confirmation hearing has not been set. Perdue is expected to easily pass through confirmation. Meanwhile, legislative work on crafting the 2018 farm bill kicks off next week. The Senate Agriculture Committee announced it will hold its first hearing on the omnibus farm legislation on February 23rd at Kansas State University, in Manhattan, Kansas, Chairman Pat Roberts' hometown. Roberts said the meeting will give him and Ranking Member Debbie Stabenow (D-MI) a chance to hear what's working and what's not.

### **Religion and Politics**

At the National Prayer Breakfast last week, Trump pledged to repeal the Johnson Amendment, a decades-old provision of tax law that prevents pastors from endorsing candidates. Rep. Steve Scalise (R-LA) and Rep. Jody Hice (R-GA) filed a bill in the House to repeal the measure, while Senator James Lankford (R-OK) introduced a companion bill in the Senate. If passed, charitable nonprofits and

foundations would be able to engage in partisan, election-related activities. In response, the National Council of Nonprofits and other representatives of the charitable community released a statement expressing strong opposition to the proposed bills.

### **Proposed New Senate Committee**

Senators Cory Gardner (R-CO) and Chris Coons (D-DE) introduced a bill to create a new Senate Select Committee on Cybersecurity. The purpose of the committee would be to oversee and strengthen U.S. data breach prevention strategy and cyber activities. It will have 21 members including the chairman and top Democrats on the Appropriations, Armed Services, Banking, Commerce, Foreign Relations, Homeland Security, and Judiciary Committees, as well as the Select Committee on Intelligence.

### **Trump's Cabinet**

The Senate confirmed three more of Trump's Cabinet nominees: Betsy DeVos as Secretary of Education, Senator Jeff Sessions (R-AL) as Attorney General, and Rep. Tom Price (R-GA) as Secretary of HHS. Status of appointees is below:

- General James Mattis for Secretary of Defense – confirmed.
- General John Kelly for Secretary of Homeland Security – confirmed.
- Rep. Mike Pompeo (R-KS) for Director of the CIA – confirmed.
- Governor Nikki Haley for Ambassador to the UN – confirmed.
- Elaine Chao for Secretary of Transportation – confirmed
- Rex Tillerson for Secretary of State – confirmed.
- Betsy DeVos for Secretary of Education – confirmed.
- Senator Jeff Sessions (R-AL) for Attorney General – confirmed.
- Rep. Tom Price (R-GA) for Secretary of Health and Human Services – confirmed.
- Steve Mnuchin for Secretary of the Treasury – hearing held, passed committee, confirmation vote scheduled for 2/13.
- David Shulkin for Secretary of Veterans Affairs – hearing held, passed committee, confirmation vote scheduled for 2/13.
- Linda McMahon for Administrator of the Small Business Administration – hearing held, passed committee, confirmation vote scheduled for 2/14.
- Ben Carson for Secretary of Housing and Urban Development – hearing held, passed committee, confirmation vote to be scheduled.
- Wilbur Ross for Secretary of Commerce – hearing held, passed committee, confirmation vote to be scheduled.
- Rep. Ryan Zinke (R-MT) for Secretary of the Interior – hearing held, passed committee, confirmation vote to be scheduled.
- Scott Pruitt for Administrator of the Environmental Protection Agency – hearing held, passed committee, confirmation vote to be scheduled.
- Governor Rick Perry for Secretary of Energy – hearing held, passed committee, confirmation vote to be scheduled.
- Rep. Mick Mulvaney (R-SC) for Director of Office of Management and Budget – hearing held, passed committee, confirmation vote to be scheduled.
- Andrew Puzder for Secretary of Labor – hearing scheduled for 2/16.
- Seema Verma for Administrator of Centers for Medicare and Medicaid Services – hearing scheduled for 2/16.
- Governor Sonny Perdue for Secretary of Agriculture – hearing to be scheduled.
- Robert Lighthizer for U.S. Trade Representative – hearing yet to be scheduled.
- Jay Clayton for Chairman of the SEC – hearing yet to be scheduled.

- Senator Dan Coats (R-IN) for Director of National Intelligence – hearing yet to be scheduled.
- Todd Ricketts for Deputy Secretary of Commerce – hearing yet to be scheduled.
- Rod J. Rosenstein for Deputy Attorney General – hearing yet to be scheduled.
- Governor Terry Branstad for Ambassador to China – hearing yet to be scheduled.
- David M. Friedman for Ambassador to Israel – hearing yet to be scheduled.
- Rep. Heather Wilson (R-NM) for Secretary of the Air Force – hearing yet to be scheduled.
- Phillip Bilden for Secretary of the Navy – hearing yet to be scheduled.
- Elaine C. Duke for Deputy Secretary of Homeland Security – hearing yet to be scheduled.