Despite the headlines coming out of Washington, Congress continues to move forward in regular fashion, discussing and acting upon key issues, such as funding the government, addressing the need to raise the debt ceiling and reauthorizing expiring programs.

While Republicans continue to seek a path forward on health and tax reform, Congress will have plenty of other items on its agenda once lawmakers return from the Memorial Day recess. In the House, Republicans intend to bring the Financial CHOICE Act, the vehicle for repealing and replacing Dodd-Frank, to the floor. In the Senate, legislators could vote on a bill to impose additional sanctions on Iran. In both chambers, transportation leaders will begin drafting Federal Aviation Administration reauthorization legislation.

Appropriators have begun initial discussions on funding the government past the end of fiscal year 2017 (FY17) in September, and the appropriations subcommittees in both chambers are awaiting their 302(b) allocations to ascertain the topline spending levels for each of the 12 annual appropriations bills. There are also indications that Congress will need to act on the debt ceiling sooner than expected. Treasury Secretary Steven Mnuchin previously stated that the Treasury’s “extraordinary measures” to stave off a U.S. debt default would be exhausted sometime in the fall, but Office of Management and Budget Director Mick Mulvaney said this month that a slower-than-expected collection of receipts could move the default date forward. Secretary Mnuchin has publicly urged lawmakers to raise the limit before leaving for their August recess.

Finally, lawmakers will begin or continue discussions in the coming months to address several expiring programs and authorizations, including the Children’s Health Insurance Program, Medicare extenders and the National Defense Authorization Act. All of this will be set to a backdrop of the several ongoing probes into Russian influence in the 2016 U.S. presidential election.

Here are some things that we believe are worth focusing on since our last issue:

1. President’s FY18 Budget Proposal
2. Tax Reform Activity Picks Up in May
3. Senate Holds Hearing to Restore Quorum at FERC
4. Obamacare Repeal Deliberations Continue in the Senate
5. FDA User Fee Packages Advance in House and Senate
6. Long Awaited Cybersecurity Executive Order Issued
7. TPP Without the United States—Where Are We Now?
8. Supreme Court Upholds Soft Money Ban
9. NAFTA Public Hearing Announced
10. Takeaways from Trump’s Middle East Trip

President’s FY18 Budget Proposal

On Tuesday, May 23, the Trump administration unveiled its $4.1 trillion 2018 budget proposal titled “A New Foundation for American Greatness.” The budget was criticized broadly by Democrats, and by many Republicans, due to steep cuts in a large number of nondefense government agencies and programs. Overall, the proposal lays out a path to balance the budget within a decade, but critics charged that these projections, which are based on an assumed accelerated economic growth rate stimulated by tax reform and regulatory relief, are highly optimistic. The budget includes proposed cuts of roughly 20 percent for the Departments of Agriculture, Labor, and Health and Human Services and roughly 30 percent cuts to the Department of State and the Environmental Protection Agency. In committee hearings and press conferences, Office of Management and Budget Director Mick Mulvaney said that President Trump had kept his campaign promise not to touch Social Security or Medicare. However, critics point to the budget’s proposed cuts to closely related programs, such as a
These nominations to FERC are especially important because, since February 3, 2017, FERC has lacked the three-commissioner quorum necessary to act on nonroutine—and often contested—matters. Such matters include the permitting of natural gas pipelines (which, among other things, is important to advancing the administration’s domestic energy agenda) and reforms to the wholesale electric markets (which is a key priority for a large and diverse mix of energy market participants). FERC also faces an unprecedented turnover, since Commissioner Colette Honorable’s term ends in June, and she has chosen not to seek renomination. This would leave Acting Chair Cheryl LaFleur as the only holdover from the previous administration, with two more commissioner seats—one Republican and one Democratic—open for the administration to fill, in addition to those to which Mr. Powelson and Mr. Chatterjee have been nominated.

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Among the topics addressed at the hearing was the issue of climate policy, as well as the impact of distributed energy resources on markets. Mr. Powelson noted that “market-based” solutions were already resulting in carbon reduction in Pennsylvania, and Mr. Chatterjee stated that any efforts to reduce carbon emissions must not undermine the reliability of the electric grid, a position consistent with FERC’s past policies reflecting its statutory mandate to preserve reliability and ensure just and reasonable wholesale electricity rates. The nominees also offered support for both the expansion of transmission infrastructure and increased exportation of liquefied natural gas.

The hearing also addressed one of the largest issues currently facing FERC: managing the impacts of state energy policies on wholesale electricity markets. FERC held a two-day technical conference on this issue in May, hoping to build a record on which it could act once it has a quorum, and the administration has ordered the Department of Energy to conduct a study looking at related issues involving federal policies. Both nominees expressed their support for a “diverse” energy mix to promote reliability, including traditional fossil fuel units, nuclear generation and renewables. They also expressed their respect for state policies, indicating that they may be willing to consider accommodating state-sponsored support for preferred generation, such as existing coal and nuclear baseload units. However, Mr. Powelson cautioned that FERC might need to step in where such programs constitute “interference in the market design.”

The committee’s Chair, Sen. Lisa Murkowski (R-AK), promised to bring the nominations to a vote swiftly so that “business can proceed” at FERC.

Obamacare Repeal Deliberations Continue in the Senate

Senate Republicans are moving forward on health care reform, and they hope to complete a partial draft during the Memorial Day congressional recess. Majority Leader Mitch McConnell (R-KY) has focused the conference’s thrice-weekly lunches on health care, while the core 13 member working group continues to meet to discuss the legislative details. Lawmakers are reportedly split over whether to include provisions that would allow states to waive essential health benefits and community rating requirements. Medicaid is another major sticking point in discussions, with no consensus yet on whether or how to roll back the Affordable Care Act’s (ACA) Medicaid expansion and adopt other reforms to the program.

Senate Republicans have indicated that they are developing their own legislative proposal, rather than working to revise the House-passed American Health Care Act (AHCA). Last week, the Congressional Budget Office (CBO) estimated that the AHCA as passed by the House would result in 23 million fewer Americans maintaining coverage compared to current law, which has continued to make the bill unpopular with health care stakeholders and the public. Additionally, the CBO estimated that the AHCA would reduce federal deficits by $119 billion over 10 years, and the Senate version will need to save a similar amount in order to comply with budget reconciliation rules. This will likely complicate senators’ efforts to expand the bill’s tax credits, include greater protections for individuals with pre-existing conditions or limit reductions in coverage under Medicaid. Leader McConnell himself has acknowledged the uphill battle in the Senate, promising a floor vote, but recognizing that he is not sure “how [they] get to 50 (votes) at the moment.”

At the same time, Health, Education, Labor and Pensions Committee Chairman Lamar Alexander (R-TN) is advocating a two-step process that would delay repeal of the ACA until 2020 while adopting short-term market stabilization measures. While a few moderate Republican senators have expressed some support for the proposal, the plan will face resistance from conservative Republicans, who are determined to repeal the ACA as soon as possible.

FDA User Fee Packages Advanced in House and Senate

Following nearly two years of negotiation and hearings examining the Generic Drug User Fee Amendments and the Biosimilar User Fee Act (BsUFA), the Prescription Drug User Fee Act, and the Medical Device User Fee Amendments, the House and Senate committees of jurisdiction have both taken significant steps to move the user fee agreements through the legislative process. Although President Trump’s budget seeks a last-minute renegotiation of user fees to make up for about a 30 percent decrease in the Food and Drug Administration’s (FDA) budget, the general consensus in both industry and Congress is that this request comes much too late for this user fee cycle and that failure to pass the already-agreed-upon reauthorizations would be devastating.

On May 18, the Subcommittee on Health of the House Energy and Commerce Committee held a markup session of the FDA Reauthorization Act of 2017 (FDARA) (H.R. 2340). The House version was initially proposed as a “clean” user fee bill, but several amendments were added to the bill during the markup. The House package now includes provisions requiring risk-based device inspections, restricting drug imports, creating a class of over-the-counter hearing aids and creating a class of “competitive generic therapies” that could be eligible for 180-day
The full House Energy and Commerce Committee is expected to hold a markup of the user fee bill in early June.

The Senate version of the FDARA passed out of committee earlier this month. The Senate package includes a 171-page Manager's Amendment to S. 934, the “clean” user fee bill introduced in April. The package is similar to the House version, but contains several riders not present in the House package, including device accessory classification, real-world evidence, pediatric drug development, generic drug product-specific bioequivalence guidance and provisions that would amend the Orphan Drug Act to address orphan drug clinical superiority (which is the subject of ongoing litigation).

Both packages will likely be considered by the full House and Senate in June.

Long Awaited Cybersecurity Executive Order Issued

On May 11, the White House issued President Trump’s long-awaited Executive Order (EO) on “Strengthening the Cybersecurity of Federal Networks and Critical Infrastructure.” The EO will have significant impacts on federal agencies, their vendors and companies owning critical infrastructure, and will have indirect impacts on many other companies. Here are a few highlights:

- The EO calls on federal agencies to focus on ways to modernize, secure and make more resilient the Federal IT systems, including through explicit risk management planning, adherence to the NIST Cybersecurity Framework and altering federal IT architecture to encourage procurement of shared IT services.

- The EO calls for the Secretary of Homeland Security, in conjunction with other agencies and the owners of critical infrastructure, to make recommendations on capabilities that agencies can employ to support critical infrastructure that has the greatest risk of attack.

- The EO calls for a number of reports to assess cyber vulnerabilities and mitigation tools for critical infrastructure operators, the Internet and the communications ecosystem, the electric grid and the defense industry. It also calls for a report on the sufficiency of federal policies to promote appropriate market transparency of cybersecurity risk management practices.

- The EO calls for a series of reports focused on ensuring “an open, interoperable, reliable and secure Internet that promotes innovation and economic activity and respects privacy and guards against disruption and criminal activity.”

The EO, which is more consistent than not with the approach of prior administrations, presents opportunities and risks for businesses that are already engaged, or would like to engage, with the federal government on information technology. For example, the EO’s call for updating federal IT systems, if funded, offers procurement opportunities, particularly for those companies that offer shared IT service solutions, as well as risks for those that do not. Among the other types of risk raised by the EO, companies that are public, especially those that provide critical infrastructure, will want to watch carefully the emerging discussion of transparency around market disclosure of cybersecurity risk management practices. These risk management practices can be challenging to describe to the public effectively and could raise concerns about an increased risk of securities litigation, among other issues.

The EO calls for a large number of agency reports, many of which will require public input and consultation. These reports will likely form the basis for future agency actions. Companies should consider engaging at the developmental stage to ensure that their business practices are taken into consideration.

The full EO is available here.

TPP Without the United States—Where Are We Now?

President Trump’s fulfillment of his campaign promise to withdraw the United States from the Trans Pacific Partnership (TPP) has left the other 11 nations in a quandary: Go back to the drawing board and renegotiate or move forward with only minor changes to provisions included in the current agreement? The remaining 11 nations have set a deadline for November 2017 as to whether they will press on with the agreed-upon framework crafted over years of intense negotiations. However, not everyone is in agreement on what the path forward will look like. Malaysia has proposed renegotiation of the deal, while Japan, Australia and New Zealand have advised against this option, promoting their commitment to the current framework of the deal and citing its “strategic and economic significance.” Economists and other trade officials have stated that, even without the U.S. participation in the deal, other countries in the Pacific Region, such as South Korea and Indonesia, will be lured into signing due to the rules based approach for a 21st century global business standard.

Without the United States, changes must be made to the agreement, specifically in regard to the clause dealing with ratification, which requires a threshold of participating nations to account for 85 percent of the collective
Supreme Court Upholds Soft Money Ban

On May 22, the Supreme Court again declined to hear a case challenging the ban on soft money contributions to political parties. The brief order issued by the high court—which did note that Justices Clarence Thomas and Neil Gorsuch favored hearing the case—affirmed the ruling of the lower court in the case of the Republican Party of Louisiana vs. the Federal Election Commission.

The Bipartisan Campaign Reform Act of 2002 (BCRA), more commonly known as the McCain-Feingold Act, banned soft money contributions to national political parties and set strict limits on the amount that state and local political parties may accept if used to influence federal elections. Prior to the passage of the BCRA, political parties could accept unlimited contributions from corporations and individuals for “party building” activities, such as get-out-the-vote efforts and issue advertisements. The amount of soft money raised by political parties increased in the late 1990s, and campaign finance reform proponents argued that the issue ads funded with soft money were indistinguishable from general campaign ads.

The Republican Party of Louisiana challenged the federal limits on soft money contributions to state and local political parties, asserting that the Federal Election Campaign Act’s regulation of state and local political parties’ independent activities is unconstitutional. Since the Supreme Court declined to hear the case in 2010, and again last week, it appears that it is up to Congress to make any changes to the current regulation of soft money.

NAFTA Public Hearing Announced

On Tuesday, May 23, the Office of the USTR issued a Federal Register notice asking for public comments on what the negotiating objectives should be for the North American Free Trade Agreement (NAFTA) renegotiation. Written comments are due by June 12, and there will be a public hearing on June 27. This is an important opportunity for clients to weigh in, not only on their priorities in NAFTA, but on trade priorities generally, since the Trump administration has indicated that the renegotiated NAFTA will serve as a template for its trade policy objectives going forward.

USTR Robert Lighthizer sent an official notice to Congress on May 19 to trigger the 90-day consultation period, as required under the Bipartisan Congressional Trade Priorities and Accountability Act of 2015. NAFTA negotiations can officially begin no earlier than August 16.

Takeaways from Trump's Middle East Trip

On May 20, President Trump began his first foreign trip as commander-in-chief with a four-day visit to Saudi Arabia, Israel and Palestine. President Trump remarked on the “good will” and “tremendous cooperation” at the Riyadh Summit, hosted by King Salman of Saudi Arabia, which representatives from 55 countries attended, including those from the Gulf Cooperation Council, as well as from Turkey, Yemen, Libya, Pakistan, Afghanistan, Iraq, Nigeria, Malaysia, Indonesia and others. The biggest news from the President’s visit was the signing of a roughly $110 billion arms deal between the United States and Saudi Arabia, including tanks; ships; missile defense systems; and various other radar, communications and cybersecurity technologies. The transfer was widely seen as part of a broader effort to counter Iranian influence in the region. Saudi Arabia also signed various business deals with U.S. companies, including General Electric and Boeing, and announced a $100 billion investment in U.S. infrastructure with Blackstone. Saudi Arabia, along with the United Arab Emirates, also made a combined $100 million donation to the World Bank’s Women Entrepreneurs Fund. President Trump concluded the Middle East portion of his trip with visits to Israel and Palestine to hold meetings with Israeli Prime Minister Benjamin Netanyahu and Palestinian Authority President Mahmoud Abbas, where he discussed ways to promote “a renewed effort at peace between the Israelis and the Palestinians.”
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