

MassBio Washington Update



December 21, 2016

Congress returned to Washington this month following unexpected election outcomes up and down the ballot. With President-Elect Donald Trump preparing to take over the Administration, lawmakers set about wrapping up several outstanding items during the lame duck session. Government funding was at the top of the agenda, and legislators passed a short-term Continuing Resolution to fund the government through April 2017. Congress also passed a long-awaited medical innovation bill as well as the annual National Defense Reauthorization Act. Lawmakers approved a bill providing aid to Flint, Michigan, and the Obama Administration began an intelligence review of possible Russian influence on the 2016 presidential election.

All of this was set to the backdrop of the President-Elect vetting and naming individuals to key positions in his incoming Administration.

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ISSUE—GOVERNMENT FUNDING

With minutes to spare, Congress averted a government shutdown when legislators approved a short-term Continuing Resolution (CR) on December 9, funding the government through April 28, 2017. The CR was necessary following lawmakers' inability to send any of the twelve annual [appropriations bills](#) to the President's desk for Fiscal Year 2017 (FY17) in 2016.

During the lame duck session, Congress debated how long the CR should last. Some appropriators called for an omnibus package that would provide full-year funding and allow for the incoming Trump Administration to begin work on the FY18 budget process. However, in his first legislative victory, President-Elect Trump convinced Republican lawmakers to support a four-month CR, giving the incoming Administration an opportunity to make its mark on the remainder of FY17 spending once Trump takes office. The House passed the measure by a vote of 326-95, with the Senate following suit, approving the legislation 63-36. The President signed the bill into law on December 10.

Coal Miners' Pensions

Prior to the bill's passage, the CR's progress stalled in early December over provisions seeking to provide a funding fix for coal miners' health and pension benefits, raising the specter of a government shutdown. Over the past year, several coal state lawmakers have advanced efforts to respond to the anticipated shortfall for United Mine Workers of America retiree benefits by transferring money from the Abandoned Mine Land Reclamation Fund to the plan, which was on the path to insolvency.

The CR included a four-month fix for retiree miners' health insurance (which was closer to insolvency than the pension side), but Democrats balked, demanding a longer extension. Senate Democrats withstood calls to drop their opposition until late in the afternoon on December 9 when they indicated they would accept the temporary patch and allow the CR to pass. Coal state legislators are expected to spend the next four months pushing for legislation in the new Congress to provide a longer-term fix.

ISSUE—HEALTH

21st Century Cures

On December 7, the Senate overwhelmingly approved the [21st Century Cures Act](#). The multi-year effort to pass the \$6.3 billion bill, which seeks to modernize the Food and Drug Administration (FDA) and the National Institute for Health (NIH), culminated in a strong bipartisan Senate vote of 94-5. The measure previously passed the House on a 392-26 vote.

Among other things, the legislation:

- Streamlines FDA approval processes by providing expedited review for breakthrough medical devices and a quickened review process for products that are both drugs and devices
- Allocates \$4.8 billion to NIH, including \$1.8 billion to Vice President Biden's "Cancer Moonshot" initiative
- Allocates \$500 million to the FDA
- Allocates additional funds for mental health and opioid addiction programs

Also included in the Cures bill was a reauthorization of the Pediatric Rare Disease Priority Review program. The program provides vouchers that pharmaceutical corporations use to obtain priority review from the FDA for qualifying experimental drugs.

As it relates to the Affordable Care Act (ACA), the Cures bill removed the prohibition on employer-sponsored healthcare reimbursement plans. Under the ACA, employers are penalized for foregoing insurance coverage in favor of arrangements in which businesses reimburse individual employee healthcare expenses. The provision included in Cures removes the daily fine for such arrangements.

Part B Demo

The outcome of the presidential election likely quashed efforts by the Centers for Medicare and Medicaid Services (CMS) to move forward with its Medicare Part B drug pricing demonstration program that funds prescription drugs administered by physicians. For regions included in the demo, the proposal would change the payment formula to include the drug's average sales price plus 2.5 percent paired with an additional flat fee of \$16.80.

Announced in March of this year, the demo immediately came under fire from Republicans and some Democrats, with both sides calling on CMS to either scrap or refine the project. The election of Donald Trump makes it unlikely that the demo will continue under the new Administration, and according to reports, House Minority Leader Nancy Pelosi (D-CA) and incoming Senate Minority Leader Chuck Schumer (D-NY) quietly asked the Obama Administration to not finalize the regulations.

ISSUE—DEFENSE POLICY

On December 2, the House approved the [FY17 National Defense Authorization Act](#) (NDAA) on a vote of 375-34. The Senate then passed the measure 92-7. The \$619 billion bill came after months of negotiations over several controversial provisions, including reallocating war funds to the Pentagon's base budget.

ISSUE—TAX

The lame duck session saw tax developments on a couple of fronts, but the main action will be next year when the tax reform debate picks up in earnest.

Tax Reform

In December, Senate Finance Chairman Orrin Hatch (R-UT) delivered remarks on the Senate floor regarding his long-discussed corporate integration proposal, which would eliminate the current system of double taxation of corporate profits that are levied first at the corporate level and then on dividends paid to shareholders. In his remarks, Chairman Hatch was encouraged by the positive feedback he has received from the Joint Committee on Taxation. While the election has altered the path forward, Chairman Hatch reiterated his commitment to the proposal and expects that it will be among the host of ideas that will be discussed during upcoming Republican efforts to reform the tax code.

Koskinen Impeachment Proceedings

During the lame duck session, the conservative House Republican Freedom Caucus sought to advance impeachment proceedings against Internal Revenue Service (IRS) Commissioner John Koskinen. The Freedom Caucus has long pursued the impeachment of Commissioner Koskinen, who conservatives believe mishandled the political targeting scandal that pre-dated his appointment and was untruthful in his testimony before Congress.

On December 6, outgoing Freedom Caucus Chairman Jim Jordan (R-OH) filed a privileged resolution to impeach Koskinen, which forced a vote on the House floor. The House voted 342-72 to refer the resolution back to the House Judiciary Committee.

Many Republicans indicated that the impeachment vote is unnecessary. Koskinen, whose term ends in November 2017, previously stated that he would step aside early if the new administration asked him to resign, which the Trump White House is expected to do.

OTHER ISSUES

Congress also completed work on the Water Resources Development Act bill during the lame duck session, and speculation increased over Russian hacking activity related to the presidential election.

Water Resources Development Act

Congress wrapped up consideration of the Water Resources Development Act (WRDA) before adjourning this month. The Senate advanced the legislation, renamed the [Water](#)

[Infrastructure Improvements for the Nation](#) (WIIN) Act, on December 10, clearing the measure for the President's signature. The bill provides financial aid to Flint, Michigan as the city continues to face a lead contamination crisis. The legislation also eases environmental restrictions on allowing officials to transfer water resources to farms and communities in central and southern California.

Russian Hacking

Following months of speculation surrounding clandestine Russian involvement in the U.S. presidential election, President Obama in December ordered a full intelligence review on Russian hacking related to the election. While the review is expected to broadly analyze malicious Russian cyber activity as far back as 2008, the Administration is particularly concerned with whether there was any Kremlin involvement in the cyberattack on Democrat-aligned groups and individuals that resulted in hacked emails being released by WikiLeaks. The final review is set to be delivered to President Obama before he leaves office.

The decision was met with mixed reactions in Washington. Democrats praised the decision and called for leaders in Congress to convene special investigations to determine if Russian actors unduly influenced the 2016 election. Donald Trump and his team blasted the decision, calling it a partisan attempt to re-litigate the outcome. On the Hill, House Speaker Paul Ryan (R-WI) and Senate Majority Leader Mitch McConnell (R-KY) have indicated support for the ongoing investigation within the intelligence community. Both leaders stated that their respective chambers' intelligence committees will thoroughly investigate the evidence. Additionally, Senate Armed Services Chairman John McCain (R-AZ), a vocal critic of Russian intervention, will add a subcommittee to investigate the cyberattacks to be led by Senator Lindsey Graham (R-SC), another strong critic of Russian aggression.

LOOKING AHEAD—BUDGET RECONCILIATION

Starting in January, Republicans will control the White House and both houses of Congress for the first in a decade. The incoming Trump Administration and Republican legislators are preparing to prioritize several items, including a repeal of the Affordable Care Act (ACA) and tax reform.

Republicans are expected to use a budget procedure known as "reconciliation" to advance ACA repeal and possibly tax reform. Reconciliation is a two-step process that first requires a budget resolution (which is non-binding and does not require the President's signature) passed by Congress that includes instructions directing committees to report statutory changes to spending, revenue, and/or debt limit levels.

In the second step, committees report their changes and the resulting legislation is put to a vote. Senate procedure limits debate over reconciliation bills to twenty hours before requiring a vote on final passage, eliminating the threat of a filibuster and allowing the legislation to pass by a simple majority.

The Senate parliamentarian previously ruled that a budget resolution can only include one set of instructions for spending, one for revenue, and one for the debt ceiling, making it unlikely that reconciliation instructions for both ACA repeal and tax reform could be included in the same budget resolution.

However, Republicans will have two shots at the budget reconciliation process in 2017. Since Congress failed to pass a budget for FY17, which runs from October 1, 2016 to September 30, 2017, lawmakers have the option to revive the FY17 budget process in January and then turn to the FY18 budget process in the spring.

The Republican plan is to adopt a FY17 budget resolution with instructions on ACA repeal in early January, beginning the reconciliation process and placing a bill repealing most of the ACA on Donald Trump's desk soon after his inauguration. The Senate is expected to begin this process. Lawmakers will then advance a separate budget resolution for FY18 with reconciliation instructions on tax reform that will likely be adopted in late spring 2017, which is consistent with the normal budget timeframe.

Republicans will not need to use the FY18 budget reconciliation process for tax reform if a bipartisan package emerges that can survive the 60-vote threshold of regular order in the Senate. If legislators fail to advance a bipartisan package, the GOP will have the FY18 budget reconciliation vehicle as a default option.

TRUMP ADMINISTRATION

Below is a chart listing the announced nominees for key Cabinet and White House posts in the forthcoming Trump Administration.

*Cabinet**

| Department/Agency | Name | Background |
|--------------------------|---------------|------------------------------|
| State | Rex Tillerson | Chairman and CEO, ExxonMobil |
| Treasury | Steve Mnuchin | Former hedge fund investor |
| Defense | James Mattis | Retired General |
| Attorney General | Jeff Sessions | U.S. Senator, Alabama |
| Interior | Ryan Zinke | U.S. Representative, Montana |
| Commerce | Wilbur Ross | Investor and former banker |
| Labor | Andrew Puzder | CEO, CKE Restaurants |
| HHS | Tom Price | U.S. Representative, Georgia |
| HUD | Ben Carson | Retired neurosurgeon |
| Transportation | Elaine Chao | Former Labor Secretary |
| Energy | Rick Perry | Governor, Texas |
| Education | Betsy DeVos | Businesswoman |
| Homeland Security | John Kelly | Retired General |

*The Trump team has yet to announce picks for Agriculture and Veterans Affairs.

*Cabinet-Level Officials***

| Position | Name | Background |
|--|----------------|---|
| White House Chief of Staff | Reince Priebus | Chairman of the Republican National Committee |
| EPA Administrator | Scott Pruitt | Attorney General, Oklahoma |
| U.N. Ambassador | Nikki Haley | Governor, South Carolina |
| Chair, Council of Economic Advisers | Gary Cohn | President and CEO, Goldman Sachs |
| Small Business Administrator | Linda McMahon | Former CEO, World Wrestling Entertainment |

**Positions listed are currently considered Cabinet-level in the Obama Administration. The incoming Trump Administration could reclassify what is considered Cabinet-level, as previous Presidents have done. The Trump team has yet to announce picks for OMB Director and Trade Representative.

RECENT POLLING

Job Approval: President Obama

| Poll | Date | Results |
|-------------------|--------|------------------------------|
| Gallup | Dec 12 | Approve 56, Disapprove 41 |
| Rasmussen Reports | Dec 12 | Approve 57, Disapprove 42 |
| McClatchy/Marist | Dec 9 | Approve 55, Disapprove 42 |

Favorability: President-Elect Trump

| Poll | Date | Results |
|--------------------------|-------|---------------------------------|
| PPP (D) | Dec 7 | Favorable 43, Unfavorable 51 |
| Reuters/Ipsos | Dec 6 | Favorable 52, Unfavorable 48 |
| The Economist/ YouGov | Dec 5 | Favorable 44, Unfavorable 52 |

Job Approval: Congress

| Poll | Date | Results |
|--------------------------|--------|------------------------------|
| PPP (D) | Dec 7 | Approve 10, Disapprove 75 |
| The Economist/ YouGov | Dec 5 | Approve 13, Disapprove 65 |
| The Atlantic | Nov 21 | Approve 17, Disapprove 73 |

Direction of the Country

| | Date | Results |
|--------------------------|-------|---|
| Rasmussen Reports | Dec 8 | Right Direction 35, Wrong Direction 55 |
| Reuters/Ipsos | Dec 6 | Right Direction 25, Wrong Direction 58 |
| The Economist/ YouGov | Dec 5 | Right Direction 26, Wrong Direction 61 |