

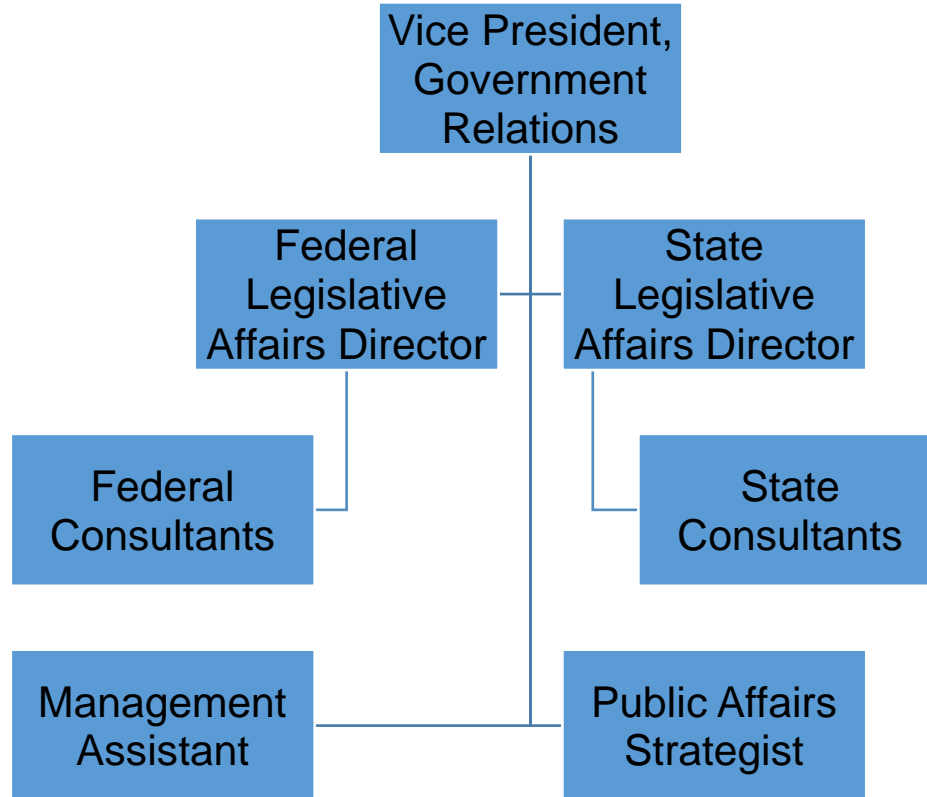
**Government Affairs Report:
Legislation and Policy Affecting Cancer Research**

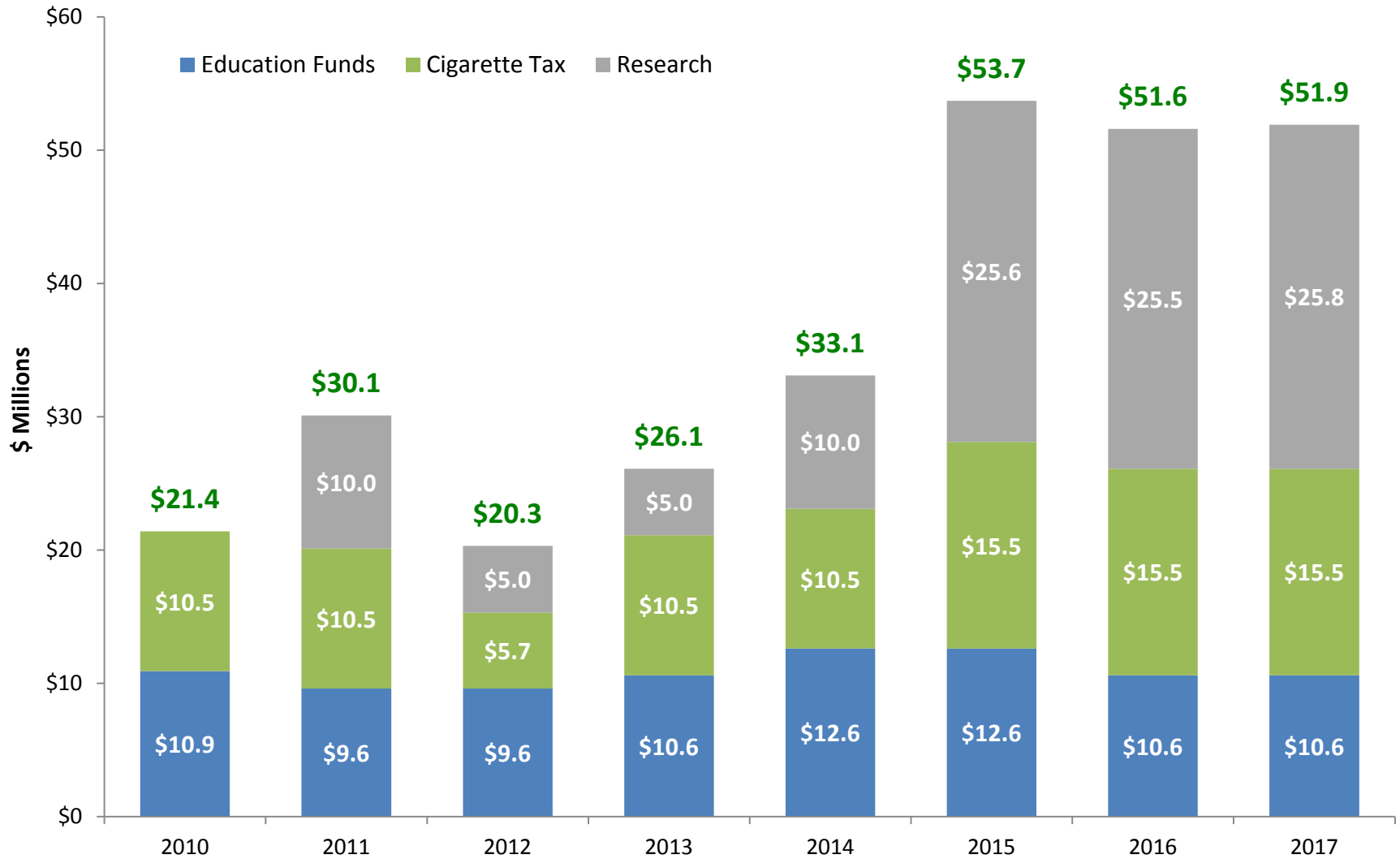
**John DeMuro, Federal Legislative Affairs Director
Moffitt Cancer Center**

Government Affairs Report: Legislation and Policy Affecting Cancer Research

Topics

- **Government Relations at Moffitt**
 - **Health Care Reform – What’s Next?**
 - **Executive Actions on Immigration**
 - **Federal Appropriations for Research**
 - **Advocacy for Science**
 - **Raising Revenue through Government Relations**
-





2017

- Health Policy Internship established for Moffitt researchers
- Provision in 21st Century Cures Bill prevents \$8M/year Medicare payment cut

2016

- NCI Director visits Moffitt
- Moffitt leaders meet with Vice President

2015

- Congress re-affirms DoD support for ORIEN
- Moffitt, ORIEN formalize partnership with Walter Reed National Military Medical Center

2014

- CCRAAB Statute updated/corrected
- Congressional Appropriations Committee offers DoD support for ORIEN

2013

- Legislation passed to extend MCC lease with USF
- HHS Secretary visits Moffitt
- U.S. Special Operations Command initiates partnership with Moffitt

2012

- Statute updated for IGT collection
- CMS updates inpatient reimbursements to dedicated cancer centers – Moffitt revenues increase by \$2-3 million/year

2011

- Medicare Outpatient adjustment adds \$5-7 million/year to Moffitt revenue

2010

- Sovereign Immunity recognized in statute
- Public Records exemption permitted indefinitely
- US Congress agrees to adjust outpatient payments to dedicated cancer centers

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Health Care Reform – What's Next?

What's next for health care?

Six questions about what is likely to happen this year



Will there be any more serious attempts to replace the ACA?

- Maybe. Any serious attempt would likely be a more minor, bipartisan, legislative fix to the ACA



Will Trump's administration undermine the ACA?

- Possibly. However, if Trump's administration does cause the law to collapse, there will likely be significant political consequences



Will Planned Parenthood be defunded in the government shutdown fight?

- Unknown. GOP hardliners in the House will require the provision; however, legislation defunding PP will not pass the Senate



Will CHIP be reauthorized in time? Will UFAs be negotiated in time?

- CHIP and other Medicare extenders will probably be passed together with the user fee agreements in a must-pass bill
- Sen. Tom Cotton suggested that the reauthorization might be linked to revisitation of ACA – this could prove very difficult and endanger the rest of the package



What about entitlement reform and drug pricing legislation?

- Entitlement reform is unlikely to occur in the next two years
- Drug pricing legislation is possible, but unlikely in the short term due to a number of other legislative priorities (e.g. tax reform, infrastructure)

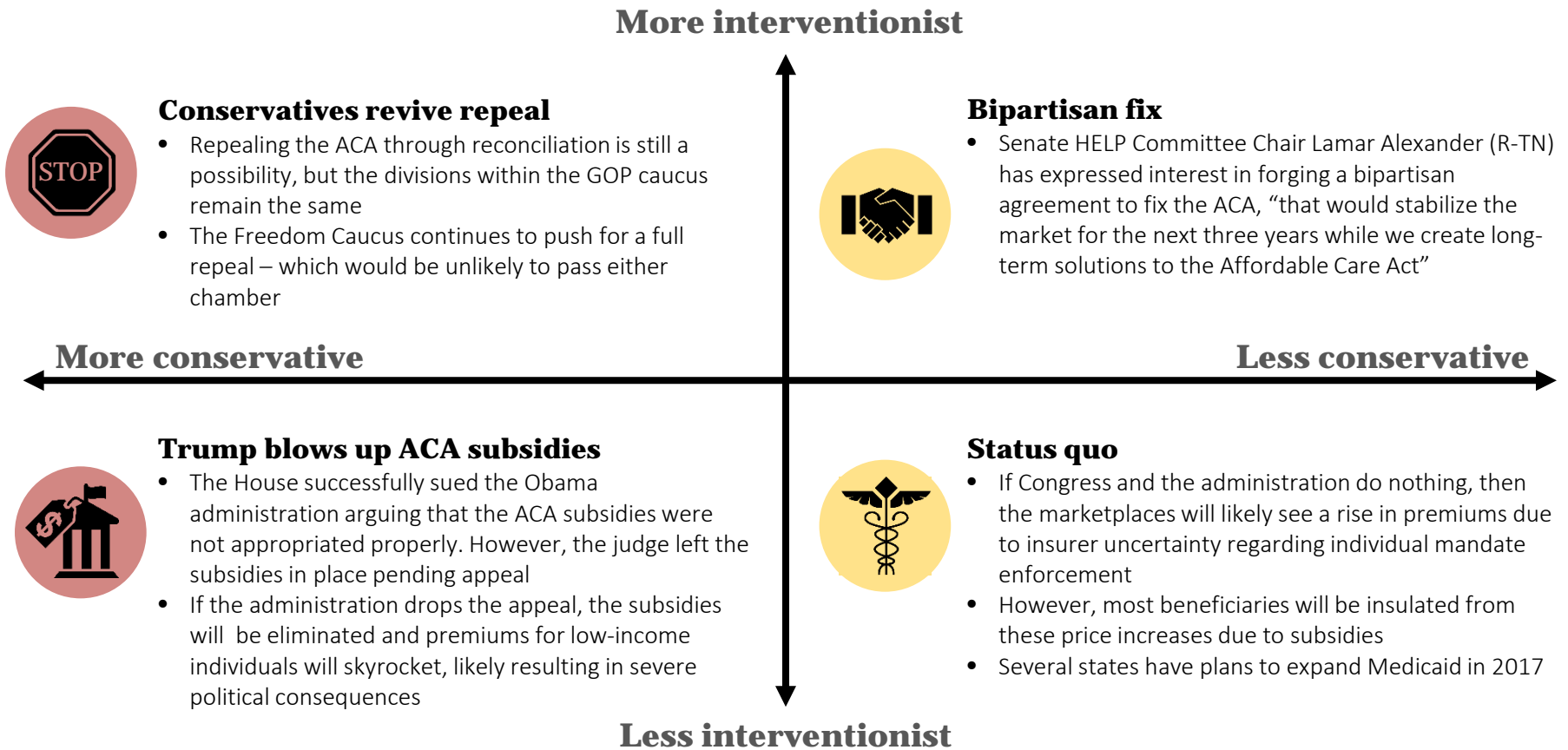


Will ACA taxes be repealed through tax reform?

- Unlikely – if tax reform is to be passed through budget reconciliation, the legislation must be budget neutral. As the GOP was unable to cut the programs that these taxes fund, they will also be unable to cut the associated taxes

ACA likely to stay, but the administration could seriously undermine it

4 scenarios going forward in health care



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Executive Actions on Immigration

President Trump’s “travel ban”

Executive Order	Date	Details
<p><i>Changing visa and refugee programs</i> Full text</p>	<p>Jan. 28, 2017</p>	<ul style="list-style-type: none"> • This directive makes significant changes to the visa and refugee programs by cutting the number of refugees allowed in the U.S. in 2017 from 110,000 to 50,000 and suspends the U.S. Refugee Admissions Program for 120 days • The order also suspends entry of “all immigrants and non-immigrants” from Iraq, Iran, Sudan, Libya, Yemen, Somalia and Syria for 90 days • It also directs the secretary of homeland security, the director of national intelligence and the secretary of state to compile a list of countries that do not provide enough information to vet potential entry of foreign nationals—these foreign nationals will be banned from entering the U.S.

Sources: “First 100 days: what executive actions has Trump take?” BBC, January 23, 2017; Kevin Liptak, “Executive orders: what Trump can and can’t do,” CNN, January 23, 2017; Michael Memoli, “Trump reopens door to building Keystone XL and Dakota Access pipelines,” LA Times, January 24, 2017.

Revised travel ban

Executive Order	Date	Details
<p><i>Revised travel ban</i> Full text</p>	<p>March 6, 2017</p>	<ul style="list-style-type: none"> • The order will go into effect 10 days from the signing of the order (on March 16th) • The order suspends the U.S. refugee program for 120 days • It announces the president’s decision to cut the number of refugees allowed in the U.S. for fiscal year 2017 from 110,000 to 50,000 (in 2016 the U.S. admitted 85,000 refugees) • The order no longer bans Syrian refugees indefinitely • Entry of nationals from Iran, Sudan, Libya, Yemen, Somalia and Syria has been suspended for 90 days—this no longer includes Iraq and does not apply to nationals with current visas, dual nationals, legal permanent residents and people with diplomatic visas • It directs the secretary of state, the secretary of homeland security, the director of national intelligence and the director of the FBI to implement a uniform screening baseline for all immigration programs • It no longer includes instruction “to prioritize refugee claims made by individuals on the basis of religious-based persecution, provided that the religion of the individual is a minority religion in the individual’s country of nationality” • It grants state and local jurisdictions a “role in the process of determining the placement or settlement” of refugees • Suspends the Visa Interview Waiver Program • It orders the DHS to implement a biometric entry-exit tracking system • It directs the secretary of state to expand the Consular Fellows Program

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Sources: “First 100 days: what executive actions has Trump take?” BBC, January 23, 2017; Kevin Liptak, “Executive orders: what Trump can and can’t do,” CNN, January 23, 2017; Aidan Quigley, “All of Trump’s executive orders so far,” POLITICO, February 6, 2017.

More executive action affecting immigration

Executive Order	Date	Details
<p><i>Buy American, hire American</i> Full text</p>	<p>April 18, 2017</p>	<ul style="list-style-type: none"> • The order combines aspects of immigration policy with federal procurement regulations to reduce guest worker visas and mandate agencies to buy more goods and services from US companies and workers • The buy American portion reinforces existing buy American acquisition rules • The hire American provision aims to reduce abuses in government guest-worker programs, particularly the H-1B visa program • The order instructs the secretaries of commerce, state and labor; the director of the Office of Management and Budget; the US trade representative; and the Federal Acquisition Regulatory Council to issue a guidance to agency heads about how to assess, monitor, enforce and implement buy American laws within their agencies

The H-1B visa program provides limited employment authorization for educated workers

Key elements of the H-1b visa program

	Specialty degree required	Organizations seeking to hire foreign workers through the H-1B visa program usually must hire a candidate with a bachelor’s degree or higher, in a field substantially related to the job in question, and for a job that requires that degree.
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	Limited stay	Visa holders can initially stay in the U.S. for three years with the possibility of an additional three-year extension; exceptions can be granted for visa holders who apply for a green card before their fifth year of holding a visa.
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	Wage equity and labor protection	Corporations hiring H-1B visa workers must hire workers at or above the “prevailing wage” in the area of employment in question, and may not hire workers to replace or fill in positions of striking workers.
<hr/>		
	Annual limits on total amount	There is a cap of 65,000 H-1B visas each fiscal year, with an additional 20,000 visas issued to immigrants who hold a master’s degree or above from a U.S. university; universities, university-affiliated non-profit research facilities, and government research facilities are exempt from this cap.

Sources: Emily Kendall, “How Long an H-1B Worker Can Stay in the United States,” NOLO Law, 2015; U.S. Citizenship and Immigration Services, “H-1B Specialty Occupations, DOD Cooperative Research and Development Project Workers, and Fashion Models,” 2015.

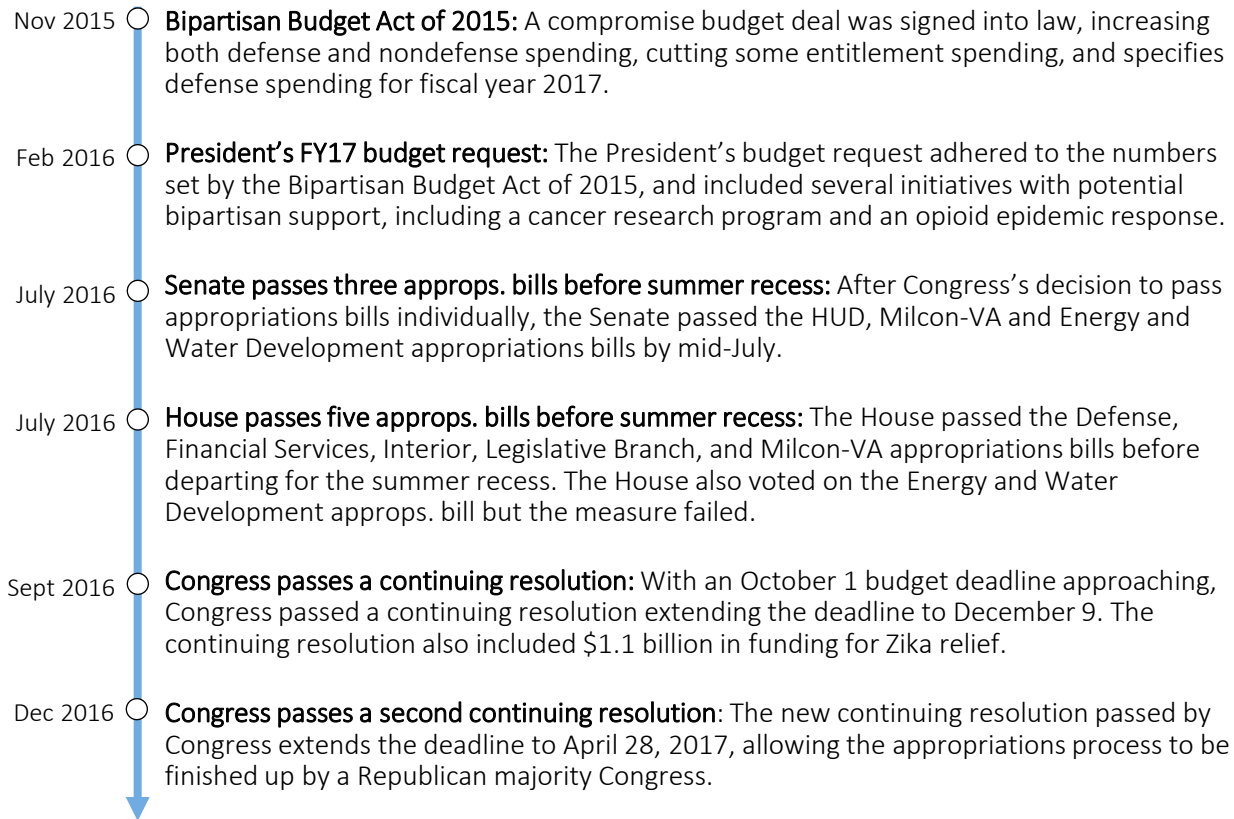
- The EO is currently not in effect. No changes have been made to the H1B Visa Program.
- The EO language exempts US Permanent Residents (green card holders).
- Students and faculty from affected countries who were already in the US and who possessed valid non-immigrant visas (i.e., visa stamps in their passports) would also be allowed to travel and re-enter the US.
- Nonetheless, students and faculty from affected countries should be extremely careful with any plans to travel outside the US.

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Federal Appropriations for Research

\$ Appropriations

Timeline of key recent federal actions on appropriations



Potential actions in 115th Congress

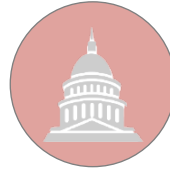
- The deadline for FY17 appropriations is set for April 28, 2017; however, Congress is expected to pass a third stopgap funding measure which will move the deadline into May
- President Trump requested \$30 billion in supplemental funding for the military in FY17 when releasing his FY2018 budget request. Several Republicans and Democrats have expressed doubt that this request will be addressed in the current appropriations process
- President Trump also requested \$1.4 billion to begin construction of the border wall, forcing appropriators for the Department of Homeland Security to revisit the bill

Appropriations - FY17

Apr
28

There are five remaining months in FY17 that need funding

Sept
30



Congress' options

Extend the current CR until Sept. 30
(flat funding for NIH at FY16 levels)

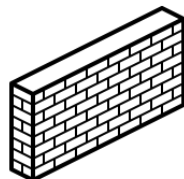
Reach agreement on an omnibus funding
package (may need stopgap spending bill)

Poison pills for Democrats

1) Defense spending hike
with domestic cuts



2) Funding for a US-
Mexico border wall



3) Defunding Planned
Parenthood



4) Restricting federal
funding for sanctuary cities



FY18 - President's Budget Request



Key provisions

- The request for \$69.0 billion for HHS is a 17.9% decrease from the 2017 annualized CR level, but includes additional funds for other priorities including implementing the 21st Century Cures Act
- The budget includes a \$500 million increase above FY2016 enacted levels to expand opioid misuse prevention and treatment efforts
- The requests includes \$25.9 billion for the NIH, a reduction of \$5.8 billion.
- Eliminates \$403 million in health professional and nurse training programs
- Changes CDC funding into a \$500 million block grant

Scrutiny for “Indirect Costs” of Research

Tom Price, Secretary, HHS

“ I was struck by one thing at NIH, and that is that about 30 percent of the grant money that goes out is used for indirect expenses, which as you know means that that money goes for something other than the research that’s being done.

“Unless you’re studying butterflies, you can’t conduct biomedical research in the middle of a field.”

Dr. Pamela Davis,
Dean, Case Western Reserve School of Medicine



Rep. Tom Cole

Chair, HHS Appropriations Subcommittee

On the proposed \$5.8 B NIH cut:

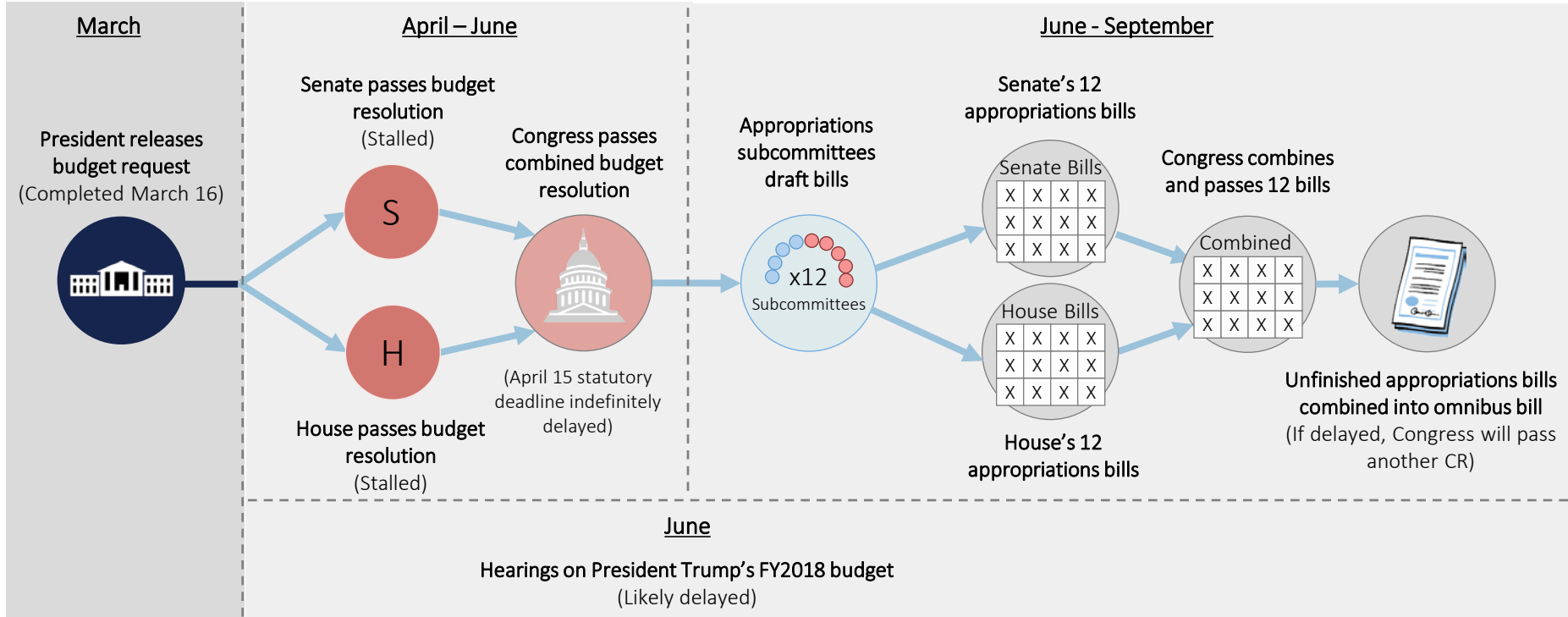
“Not going to happen.”

On Indirects:

“We look forward to working to find ways to stretch those dollars further.”

A spending battle over Trump's FY2018 looms ahead of the start of the fiscal year on Oct. 1

Current status of FY2018 budget negotiations



Analysis

- Before the FY2018 budget battle begins, Congress has to clear the threat of a government shutdown on April 28th
- They likely will pass another CR, extending the deadline until May or potentially September, allowing time for drafting and conferencing FY2018 appropriations bills before the start of FY2018 on October 1

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Advocacy for Science

Advocacy for Science



Making Your Voice Heard

Patient & Family Involvement



DC Fly-ins



Lab tours



Media relations



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Raising Revenue through Government Relations



Allocations from Partnerships with Government

- Department of Defense
- Veteran's Affairs

“Research Advancement”

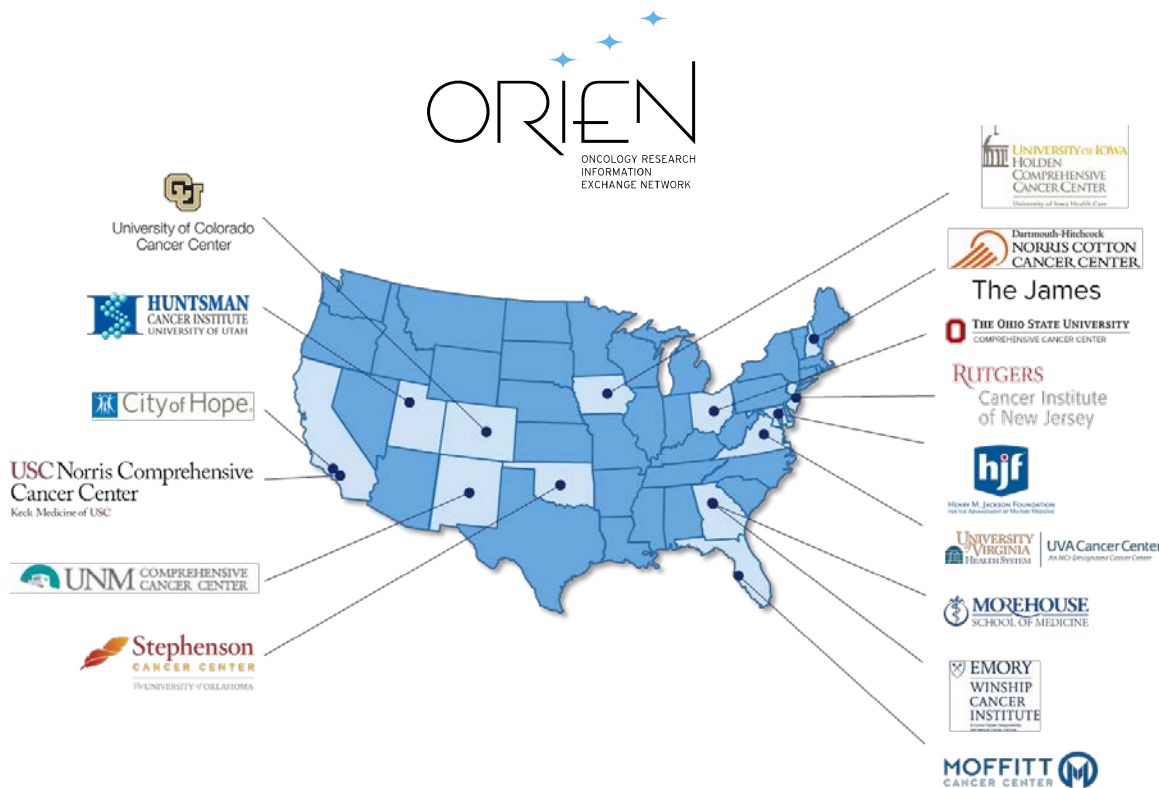
- Influencing Grant Programs
- Working with Congress and Agencies

Profile-Raising

- Executive Branch
 - Congressional Committees
 - National Media
-

Oncology Research Information Exchange Network (ORIEN)

Moffitt currently partners with fifteen of the nation's leading cancer centers to deliver informatics based solutions to accelerate therapy discovery and development via the Oncology Research Information Exchange Network (ORIEN)



- A national alliance to integrate “Big Data” for cancer research
- All ORIEN Members use same protocol for consenting and data-sharing
- 170,000 patients consented to date



Tobacco Tax Collections

Higher Education

Economic Development

Public Health

Special Programs

