

## Research!America Alliance Member Meeting Recap

August 29, 2017 1-2pm (Dirksen 430)

### Meeting with Senate HELP Committee Regarding NIH, FDA, CDC, and AHRQ Portfolios

#### Guest Speakers:

Grace Stuntz, Senior FDA Policy Advisor, Majority Senate HELP Committee  
Margaret Coulter, Health Professional Staff Member, Majority Senate HELP Committee  
Kristi Thompson, Professional Staff Member, Majority Senate HELP Committee  
Andrew Vogt, Professional Staff Member, Majority Senate HELP Committee  
Remy Brim, Senior FDA Counsel, Minority Senate HELP Committee  
Madeleine Pannell, Health Policy Advisor, Minority Senate HELP Committee

*Note: This recap does not capture every question and comment, but we tried to touch on each of the major themes of the discussion.*

#### **Health Insurance Market Stabilization**

- The Senate HELP Committee has announced a series of hearings, September 6 and 7, to address the stabilization of individual health insurance markets
- State Insurance Commissioners testifying on 9/6 and Governors testifying on 9/7
- Want to see a bipartisan bill by the end of September

#### **21<sup>st</sup> Century Cures Oversight**

- Continued oversight of 21<sup>st</sup> Century Cures (21<sup>st</sup> CC) implementation, welcome our thoughts on FDA's progress and would appreciate it if we would let them know about any implementation issues we become aware of
- Working closely with NIH and FDA leaders to ensure the legislation is enacted as intended
- The NIH and FDA have responded to current deadlines, but most are still ahead

#### **Drug Pricing**

- Chairman Alexander and Ranking Member Murray are working together and plan to continue exploring the various factors influencing current pricing. There may be additional hearings this Fall in conjunction with the release of a National Academy of Medicine report on the topic
- Has been useful for the Committee to hear from different stakeholders within the supply chain
- Committed to looking at the ecosystem to determine where improvements can be made

#### **Regenerative Medicine**

- Chairman Alexander and Ranking Member Murray were pleased with Dr. Gottlieb's recent action to ensure proper regulation of all entities engaged in cell therapy
- The HELP Committee worked hard on a bipartisan basis to ensure the regenerative therapy provisions in 21<sup>st</sup> CC set the stage for clarity and efficiency in the regulation of regenerative therapies without jeopardizing sound regulation of these therapies
- A priority will be to establish clear rules of the road with a particular emphasis on ensuring clarity for small companies working with the FDA for the first time
- Would appreciate hearing from stakeholders about their priorities and interests in this arena

### **CDC Standing Fund**

- Committee is prepared for a robust conversation on the establishment of standing emergency funds
- Given the state of an existing emergency fund that has not been funded since early 2000's, the committee needs to look carefully at the best path forward and welcomes input.
- Committee understands the benefit of having funds on hand instead of asking Congress for supplemental funding

### **Right to Try**

- Legislation passed by unanimous consent in the Senate and is awaiting action in the House
- Chairman Alexander and Ranking Member Murray played a significant role in working out a compromise – the bill that passed is very different than the bill that was introduced

### **Opioid Epidemic**

- Committee will carefully monitor implementation and impact of the Comprehensive Addiction and Recovery Act (CARA)
- Research to help pain patients, including research into non-addictive pain treatments is an important piece of the puzzle.
- A priority for Ranking Member Murray is to secure passage of the Medicaid Access and CHIP Reauthorization Act (MACRA), in part to ensure continuity in funding for the frontline workforce providing opioid care, particularly in rural areas

### **NIH Funding Cuts and Indirect Cost Changes**

- Members of the HELP Committee want to protect the NIH and scientific research
- Chairman Alexander has been vocal in his opposition to the Administration's indirect cost proposal
- The Chair and Ranking Member are both committed to ensuring NIH can continue to support life-saving research, and the funding passed as part of 21<sup>st</sup> Century Cures is indicative of broad-based Congressional support
- It makes sense to understand better the nature and scope of the issue, but not to jeopardize crucial research

### **NIH Reclassification of Clinical Trials**

- Reclassification of some studies as clinical trials that were formerly classified as basic research is on the HELP Committee's radar, but there is no immediate action plan
- The Committee is interested in receiving resources and hearing from stakeholders on this topic

### **Upcoming Bills**

- Reauthorization of the Pandemic All Hazards Preparedness Act (PAHPA) and Animal Drug User Fees