### Epidemiology and the Federal Government: A Critical but Fragile Partnership

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#### **Michael Stephens**

38 years experience in legislative, budget and advocacy worlds;

Founding Director Summer 2014, ACT for NIH and Friends of Medical Research PAC

Founder, RayburnBC, Inc.

### Goals for Today's Discussion

- Better understand the federal partnership.
- Review the current crisis in NIH funding.
- Understand the political process/ players/ timing.
- Learn about the current advocacy.
- (fact of the day 6352 of the 50,000 active research grants at NIH have term epidemiology in title. Virtually all NIH IC's have an epidemiology branch or division.)

# What is at stake for the epidemiology in Washington policy world? Why You should care?

- Use of epidemiology as core tool for evidence based science and public health policy.
- Funding!!
- Fair treatment of epidemiology in allocation of resources.
- Training of next generation.
- And more....

#### The current environment:

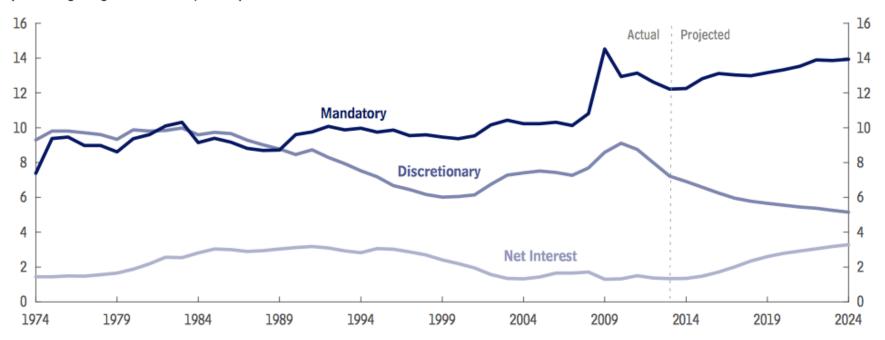
- Macro budget concerns. (The Deficit)
- Partisan politics.
- Less informed and analytic policy process.
- Lack of continuity and stability.
- NIH science and leadership highly respected.
- Core strength: executive branch at NIH/CDC.

### Outlays – CBO (2/14)

Figure 3-1.

#### **Outlays, by Category**

(Percentage of gross domestic product)

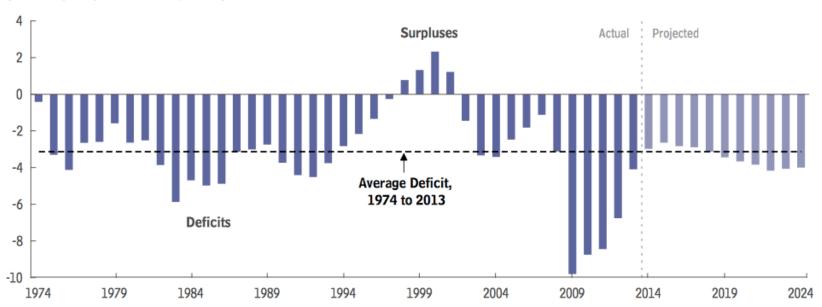


#### Federal Deficit – CBO (2/14)

Figure 1-1.

#### **Total Deficits or Surpluses**

(Percentage of gross domestic product)



Source: Congressional Budget Office.

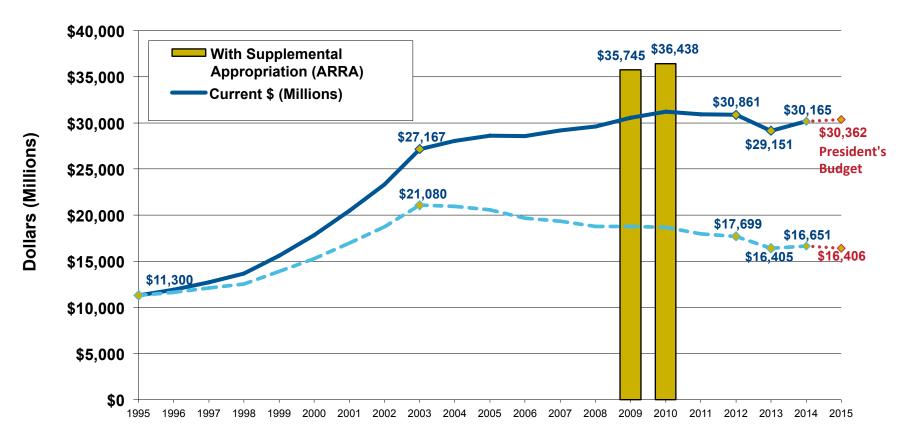
### BCA Caps slide

### Omnibus Budget Agreement

|                 | Full Year FY 2013<br>Discretionary<br>Spending<br>(Sequestration) | FY 2014<br>Discretionary<br>Spending Cap<br>(Sequestration) | FY 2014<br>Discretionary<br>Spending Cap<br>(Budget Deal) | FY 2015<br>Discretionary<br>Spending Cap<br>(Budget Deal) |
|-----------------|---|---|---|---|
| Defense         | \$518 billion   | \$498 billion   | \$520.46 billion  | \$521 billion   |
| Non-<br>Defense | \$468 billion   | \$469 billion   | \$491.77 billion  | \$492 billion   |
| Total           | \$986 billion   | \$967 billion   | \$1.012 trillion  | \$1.014 trillion  |

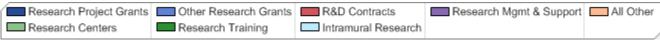
#### **NIH Appropriations in Current and Constant Dollars**

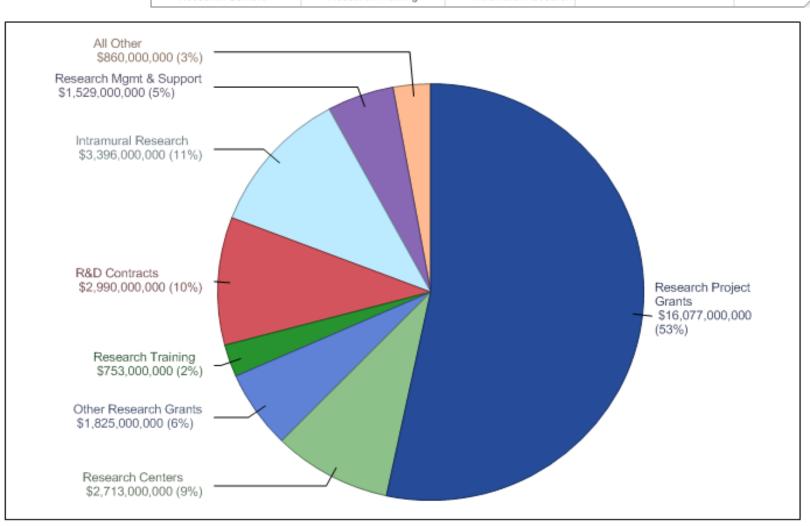
(2003 - 10,411 new grants; 2013 – 8236 new grants. reduced 21 %)



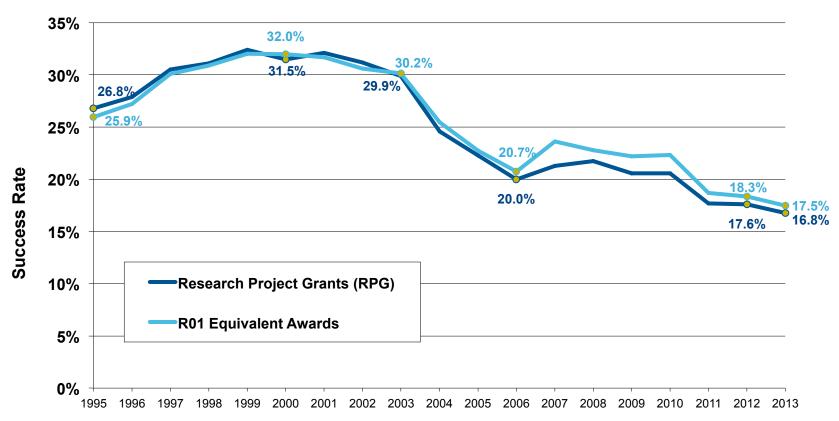
Source: NIH Office of the Director, Office of Budget: http://officeofbudget.od.nih.gov/

#### Total NIH budget authority FY 2014 enacted



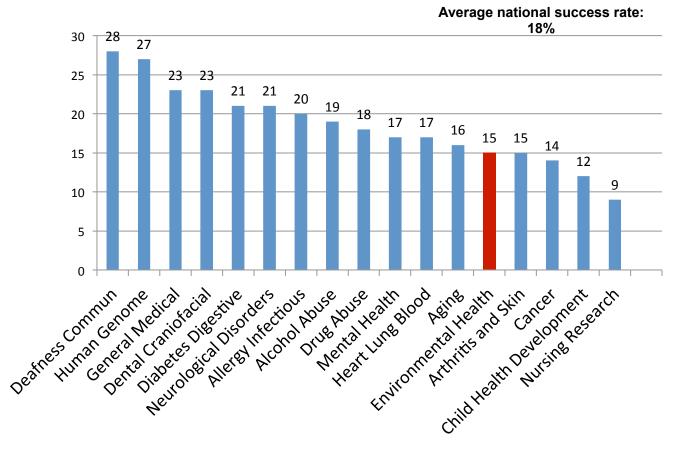


#### **Success Rates (Excluding ARRA)**



Source: NIH Data Book <a href="http://report.nih.gov/nihdatabook/index.aspx">http://report.nih.gov/nihdatabook/index.aspx</a> and supplemental tables available in *RePORT* 

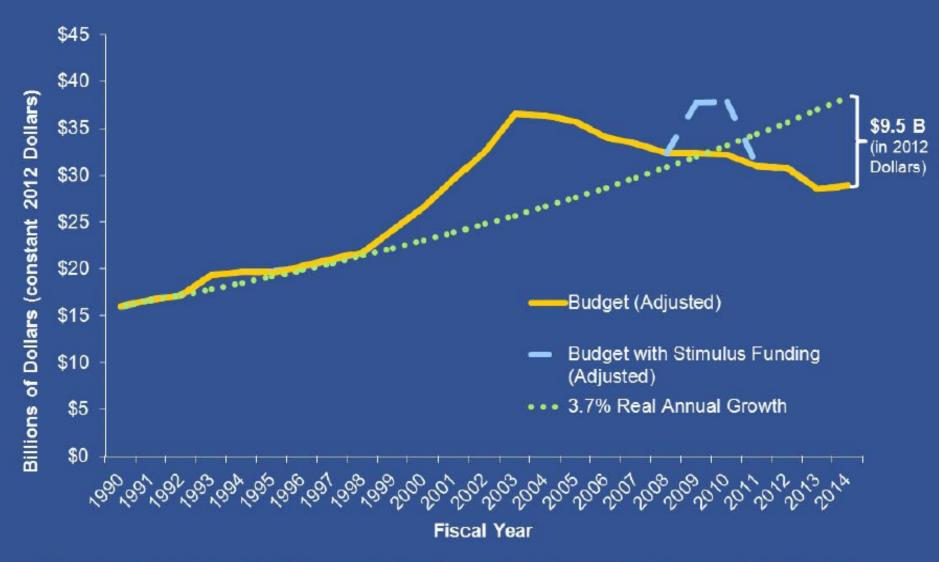
### Examples of National Success Rates by NIH Institute, 2011



### **Summary of Trends in NIH Funding FY1995-FY2013**

|                                      | FY2003   | FY2013   | % Change since 2003 |
|--------------------------------------|----------|----------|---------------------|
| NIH Budget<br>(in millions)          | \$27,067 | \$29,151 | 7.7%                |
| NIH Budget<br>(constant \$'s)        | \$21,003 | \$16,309 | -22.4%              |
| R01 Equivalent Funding (\$ millions) | \$10,102 | \$10,175 | 0.7%                |
| Total # R01 Equivalent Grants        | 29,626   | 25,069   | -15.4%              |
| R01 Equivalent Applications          | 24,634   | 28,044   | 13.8%               |
| # of R01 Equivalent Awards           | 7,430    | 4,902    | -34.0%              |
| R01 Equivalent Success Rates         | 30.2%    | 17.5%    | -42.0%              |

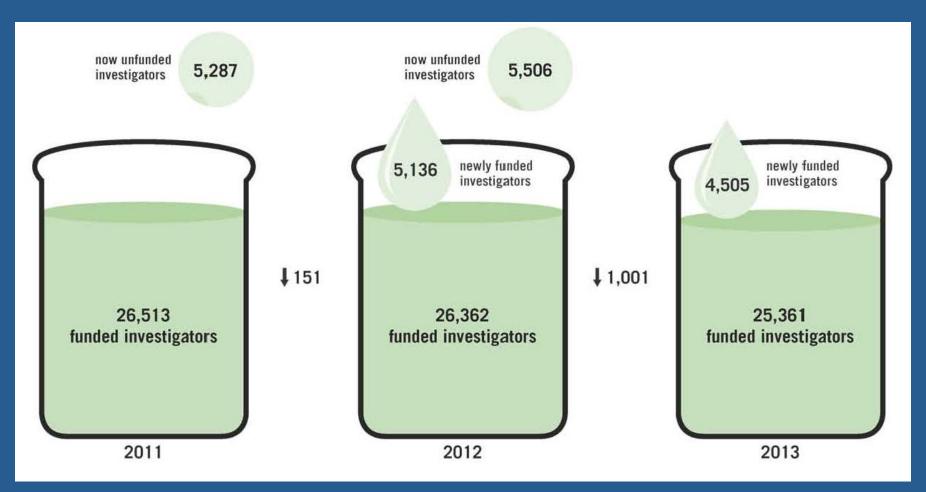
## National Institutes of Health Funding



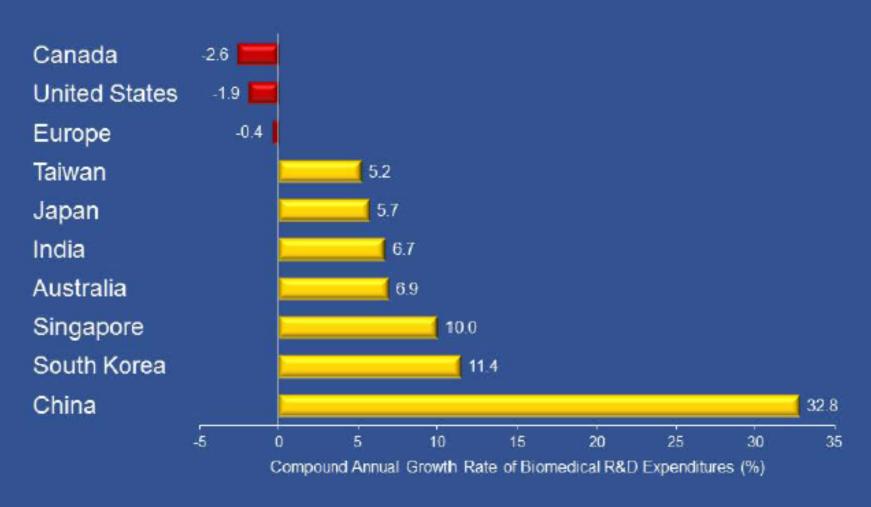
Note: The 3.7 % Real Annual Growth is based on average real growth between 1971 and 1997. Dollar values are adjusted to 2012 Dollars using the Biomedical Research and Development Price Index (BRDPI), http://officeofbudget.od.nih.gov/gbiPriceIndexes.html.

Source: NIH Office of Extramural Research and Office of Budget source data (March 29, 2014)

### Sequester's Toll: 1,000 Fewer Investigators



#### Compound Annual Growth Rate of Biomedical R&D Expenditures by Country, Adjusted for Inflation 2007–2012



Source: N Engl J Med. 2014 Jan 2;370(1):3-6

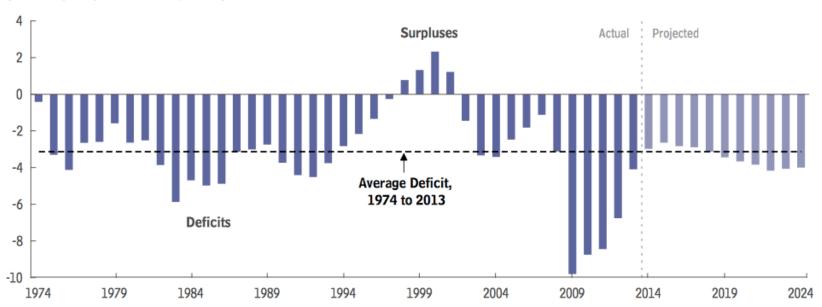


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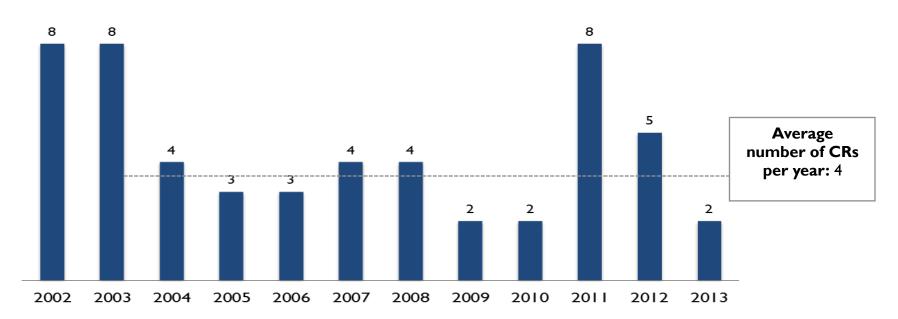
Source: Congressional Budget Office.



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#### In Practice, Continuing Resolutions Now Common

#### Number of Continuing Resolutions Passed, by Fiscal Year



#### **Analysis**

Source: Kenneth Chamberlain, "Congress' Use of Continuing Resolutions Is a Common Practice," National Journal, Sept. 11, 2013; "Continuing Resolutions: CRs in a Nutshell," Department of the Treasury, 2012.

<sup>•</sup>A continuing resolution (CR) is a stopgap measure that authorizes continued government funding for federal agencies or specific programs at, above, or below current funding levels when Congress and the president do not pass a regular appropriations bills before the fiscal year begins

<sup>•</sup>CRs can be attractive vehicles for other substantive legislation because they are considered "must-pass" measures, but passing a CR in lieu of a budget resolution also produces budget uncertainty, making it difficult to act on other legislative priorities

# Will Congress Do Something? Maybe!

- Growing sense of the crisis in NIH funding.
- NIH viewed as well managed & good investment.
- Bi-partisan support strong and growing.
- Budget Caps need to be modified 2016.
- But, partisanship and the continuing focus on deficits remain powerful factors.
- Large turnover of Congressional NIH leadership.
- Who will lead?

### Many Republicans Are Supportive

- "This is the time of promise in research and the United States should be at the forefront in this era. To do so we must commit to pay for the research."
  - Sen. Jerry Moran (R-KS)
- "Our basic money we spend in research is not enough, and we are leaving a lot of ideas and lot of, perhaps, breakthroughs, on the table and we can't afford that as a nation."
  - Sen. Richard Shelby (R-AL)

### **Democrats Are Supportive**

- "NIH is being forced to do less with less....The cuts have a direct, a devastating impact on innovative medical research that saves lives, that boosts our economy."
  - Rep. Rosa DeLauro (D-CT)
- "If America is going to remain the world's leader in cuttingedge biomedical research, we must make federal funding for medical research a national priority."
  - Sen. Richard Durbin (D-IL)

### Some Republicans Are Skeptical

- "I support the NIH's core responsibility of basic research, but believe it should stop the frivolous, politically motivated and wasteful grants it has been funding."
  - Rep. Jack Kingston (R-GA)
- "Why are we spending that much per person [on AIDS] when we have other diseases that afflict more people?"
  - Rep. Andy Harris (R-MD)

### A small number can make a huge difference

#### House of Representatives



Rep. Nita Lowey

(D-NY)



Rep. Rosa DeLauro (D-CT)



Rep. Fred Upton (R-MI)



Rep. Debbie Wasserman Schultz (D-FL)



(R-KY)



Rep. Hal Rogers Rep. John Boehner (R-OH)



Rep. Eric Cantor (R-VA)

#### Senate



Sen. Tom Harkin (D-IA)



Sen. Dick Durbin (D-IL)



Sen. Barbara Mikulski (D-



Sen. Harry Reid (D-NV)



Sen. Patty Murray



Sen. Jerry Moran (R-KS)



Sen. Richard Shelby (R-AL)



Sen. Mitch McConnell (R-KY)

### The Congressional Line-Up

|                                  | 113 <sup>th</sup> Congress | November 4 Election |
|----------------------------------|----------------------------|---------------------|
| SENATE                           |                            |                     |
| <ul> <li>Democrats</li> </ul>    | 53                         | 20                  |
| <ul> <li>Republicans</li> </ul>  | 45                         | 13                  |
| <ul> <li>Independents</li> </ul> | 2                          |                     |
| HOUSE                            |                            |                     |
| <ul> <li>Democrats</li> </ul>    | 199                        | 199                 |
| <ul> <li>Republicans</li> </ul>  | 233                        | 233                 |
| <ul> <li>Vacant</li> </ul>       | 3                          | 3                   |



### House Committee on Appropriations



Rep. Hal Rogers (R-KY)



Rep. Nita M. Lowey (D-NY)

| Majority (R) (29)            | Minority (D) (22)                 |
|------------------------------|-----------------------------------|
|                              |                                   |
| Harold Rogers, Kv Chairman   | Nita M. Lowey, N.Y Ranking Member |
| Frank R. Wolf, Va.           | Marcy Kaptur, Ohio                |
| Jack Kingston, Ga.           | Peter J. Visclosky, Ind.          |
| Rodney Frelinghuysen, N.J.   | José E. Serrano, N.Y.             |
| Tom Latham, Iowa             | Rosa DeLauro, Conn.               |
| Robert B. Aderholt, Ala.     | James P. Moran, Va.               |
| Kay Granger, Texas           | Ed Pastor, Ariz.                  |
| Mike Simpson, Idaho          | David E. Price, N.C.              |
| John Culberson, Texas        | Lucille Roybal-Allard, Calif.     |
| Ander Crenshaw, Fla.         | Sam Farr, Calif.                  |
| John Carter, Texas           | Chaka Fattah, Pa.                 |
| Ken Calvert, Calif.          | Sanford D. Bishop Jr., Ga.        |
| Tom Cole, Okla.              | Barbara Lee, Calif.               |
| Mario Diaz-Balart, Fla.      | Adam B. Schiff, Calif.            |
| Charlie Dent, Pa.            | Michael M. Honda, Calif.          |
| Tom Graves, Ga.              | Betty McCollum, Minn.             |
| Kevin Yoder, Kan.            | Tim Ryan, Ohio                    |
| Steve Womack, Ark.           | Debbie Wasserman Schultz, Fla.    |
| Alan Nunnelee, Miss.         | Henry Cuellar, Texas              |
| Jeff Fortenberry, Neb.       | Chellie Pingree, Maine            |
| Tom Rooney, Fla.             | Mike Quigley, Ill.                |
| Chuck Fleischmann, Tenn.     | Bill Owens, N.Y.                  |
|                              |                                   |
| Jaime Herrera Beutler, Wash. |                                   |
| David Joyce, Ohio            |                                   |
| David Valadao, Calif.        |                                   |
| Andy Harris, Md.             |                                   |
| Mark Amodei, Nev.            |                                   |
| Martha Roby, Ala.            | Running for Other Office          |
| Chris Stewart, Utah          | Announced Retirement              |

### Senate Committee on Appropriations



Sen. Barbara Mikulski (D-MD)



Sen. Richard Shelby (R-AL)

| Majority (D) (16)           | Minority (R) (14)                       |
|-----------------------------|---|
| Mikulski, Barbara A. (MD) , | Shelby, Richard C. (AL), Ranking Member |
| Chairman                    |   |
| Leahy, Patrick J. (VT)      | Cochran, Thad (MS)                      |
| Harkin, Tom (IA)            | McConnell, Mitch (KY)                   |
| Murray, Patty (WA)          | Alexander, Lamar (TN)                   |
| Feinstein, Dianne (CA)      | Collins, Susan M. (ME)                  |
| Durbin, Richard J. (IL)     | Murkowski, Lisa (AK)                    |
| Johnson, Tim (SD)           | Graham, Lindsey (SC)                    |
| Landrieu, Mary L. (LA)      | Kirk, Mark (IL)                         |
| Reed, Jack (RI)             | Coats, Daniel (IN)                      |
| Pryor, Mark L. (AR)         | Blunt, Roy (MO)                         |
| Tester, Jon (MT)            | Moran, Jerry (KS)                       |
| Udall, Tom (NM)             | Hoeven, John (ND)                       |
| Shaheen, Jeanne (NH)        | Johanns, Mike (NE)                      |
| Merkley, Jeff (OR)          | Boozman, John (AR)                      |
| Begich, Mark (AK)           |   |
| Coons, Christopher A. (DE)  | Announced Retirement                    |

#### House Committee on Energy & Commerce



Rep. Fred Upton (R-MI)

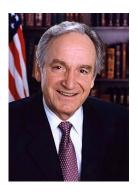


Rep. Henry Waxman (D-CA)

| Majority (R ) (30)              | Minority (D) (23)          |
|---------------------------------|----------------------------|
| Rep Fred Upton (MI)             | Rep Henry Waxman (CA)      |
| Rep Joe Barton (TX)             | Rep John Dingell (MI)      |
| Rep Ed Whitfield (KY)           | Rep Frank Pallone (NJ)     |
| Rep John Shimkus (IL)           | Rep Bobby Rush (IL)        |
| Rep Joe Pitts (PA)              | Rep Anna Eshoo (CA)        |
| Rep Greg Walden (OR)            | Rep Eliot Engel (NY)       |
| Rep Lee Terry (NE)              | Rep Gene Green (TX)        |
| Rep Mike Rogers (MI)            | Rep Diana DeGette (CO)     |
| Rep Tim Murphy (PA)             | Rep Lois Capps (CA)        |
| Rep Michael Burgess (TX)        | Rep Mike Doyle (PA)        |
| Rep Marsha Blackburn (TN)       | Rep Jan Schakowsky (IL)    |
| Rep Steve Scalise (LA)          | Rep Jim Matheson (UT)      |
| Rep Bob Latta (OH)              | Rep G.K. Butterfield (NC)  |
| Rep Cathy McMorris Rodgers (WA) | Rep John Barrow (GA)       |
| Rep Gregg Harper (MS)           | Rep Doris Matsui (CA)      |
| Rep Leonard Lance (NJ)          | Rep Donna Christensen (VI) |
| Rep Bill Cassidy (LA)           | Rep Kathy Castor (FL)      |
| Rep Brett Guthrie (KY)          | Rep John Sarbanes (MD)     |
| Rep Pete Olson (TX)             | Rep Jerry McNerney (CA)    |
| Rep David McKinley (WV)         | Rep Bruce Braley (IA)      |
| Rep Cory Gardner (CO)           | Rep Peter Welch (VT)       |
| Rep Mike Pompeo (KS)            | Rep Ben Ray Luján (NM)     |
| Rep Adam Kinzinger (IL)         | Rep Paul Tonko (NY)        |
| Rep Morgan Griffith (VA)        |                            |
| Rep Ralph Hall (TX)             |                            |
| Rep Phil Gingrey (GA)           |                            |
| Rep Gus Bilirakis (FL)          |                            |
| Rep Bill Johnson (OH)           |                            |
| Rep Billy Long (MO)             | Running for Other Office   |
| Rep Renee Ellmers (NC)          | Announced Retirement       |



#### Senate HELP Committee



Sen. Tom Harkin (D-IA)



Sen. Lamar Alexander (R-TN)

| Majority (D) (12)          | Minority (R) (10)                     |
|----------------------------|---------------------------------------|
| Harkin, Tom (IA), Chairman | Alexander, Lamar (TN), Ranking Member |
| Mikulski, Barbara A. (MD)  | Enzi, Michael B. (WY)                 |
| Murray, Patty (WA)         | Burr, Richard (NC)                    |
| Sanders, Bernard (VT)      | Isakson, Johnny (GA)                  |
| Casey, Robert P. (PA)      | Paul, Rand (KY)                       |
| Hagan, Kay R. (NC)         | Hatch, Orrin G. (UT)                  |
| Franken, Al (MN)           | Roberts, Pat (KS)                     |
| Bennet, Michael F. (CO)    | Murkowski, Lisa (AK)                  |
| Whitehouse, Sheldon (RI)   | Kirk, Mark (IL)                       |
| Baldwin, Tammy (WI)        | Scott, Tim (SC)                       |
| Murphy, Christopher (CT)   |                                       |
| Warren, Elizabeth (MA)     | Announced Retirement                  |



#### **Executive Branch Partners**

#### Department of Health and Human Services





Secretary Sylvia Mathews Burwell

















Director of NIH Dr. Francis Collins



Director of CDC Dr. Thomas Frieden



Administrator of HRSA Dr. Mary Wakefield



Director of AHRQ Dr. Richard Kronick



Commissioner of FDA Dr. Margaret Hamburg



Administrator of USAID Dr. Rajiv Shah



Secretary of Agriculture Tom Vilsack

### NIH: Steady, Predictable Growth

 "The doubling did huge things for biomedical research. But, what came after has been really quite painful.... [W]hat would be vastly better ... would be for us to be able to count on a more or less stable trajectory of inflation plus some percentage that you could be fairly confident was going to be maintained."

NIH Director Francis Collins
 April 2, 2014, Senate Hearing

#### NIH Strategic Plan for Prevention



#### STRATEGIC PRIORITY I

Systematically monitor NIH investments in prevention research and assess the progress and results of that research.



#### STRATEGIC PRIORITY II

Identify prevention research areas for investment or expanded effort by the NIH.



#### STRATEGIC PRIORITY III

Promote the use of the best available methods in prevention research and support the development of better methods.



#### STRATEGIC PRIORITY IV

Promote collaborative prevention research projects and facilitate coordination of such projects across the NIH and with other public and private entities.



#### STRATEGIC PRIORITY V

Identify and promote the use of evidence-based interventions and promote the conduct of implementation and dissemination research in prevention.



#### STRATEGIC PRIORITY VI

Increase the visibility of prevention research at the NIH and across the country.



### 21st Cures and "NIH Reform"

- Bi-partisan review led by authorizing committees. Upton & DeGette
- Prioritization process
- Mechanisms of support
- New partnerships
- ROI enhancements
- Opportunity and risk!

### New advocacy efforts

- Traditional groups more energized scientists, research institutions, disease groups.
- More powerful engagement by executive branch leaders on needs and opportunities.
- New Congressional leadership potentially emerging.
- New, highly focused outside advocacy efforts.
   (ACT for NIH Advancing Cures Today & Friends of Medical Research PAC)