21st Century Cures, HR 6

Lizbet Boroughs
American Association of Universities
HR 6: NIH Provisions

• **Overview of Title I, NIH:**
  - Contributes to the momentum of support for NIH
    - Establishes research as a national priority
    - Sets goals for increased funding
    - Raises expectations and creates target for advocacy
  - Establishes new programs and directions
    - Some are helpful – reduce administrative burden
    - Others may be duplicative, unnecessary
    - Problematic – Overly prescriptive, creates new mandates
  - Potential of accepting new requirements without receiving actual funding
HR 6: NIH Provisions

- NIH Innovation Fund
- NIH Strategic Plan
- Increased Accountability
  - I/C Director review of all research grant awards
  - IOM Study on Duplication in Biomedical research
  - Increase minority enrollment in studies and trials
  - Consider suggestions of regulatory burden groups
HR 6, 21st Century Cures

Association of American Universities
HR 6: NIH Provisions

- High-Risk, High-Reward Research Program
  - Established in each I/C
  - Specific percentage of budget set aside by Director of NIH

- Accelerating Advancement Program
  - Dollar match by I/C for every dollar from Director

- Supporting Emerging Scientists
  - Increased loan forgiveness $35k to $50k

- Capstone Award program
HR 6: NIH Provisions

- Accelerating Advancement Program (must be matched by I/C): 25%
- Early Stage Investigator (within 10 yrs of degree or res.): 26%
- Intramural Program: 10%
- High Risk, High Reward: 15%
- Other Investigator-Initiated, Early Career, or Small Business: 24%

Assumes:
1) Maximum for Intramural
2) Minimum for AAP
HR 6: NIH Provisions

- Promote Pediatric research
  - Establish National Pediatric Research network
  - Global Pediatric Clinical Study network (sense of Congress)

- Establish National Surveillance Network of Neurological Diseases (CDC)

- Require NIH to issue of guidance on use of single IRB for multi-site research
HR 6: NIH Provisions

- Data Access
  
  NIH Director “may” require data sharing
  - Standardization of data in clinical trials data bank
  - Clinical trial data system (7 year pilot program)
  - National Surveillance Network of Neurological Diseases (CDC)
  - Require issue of guidance on use of single IRB for multi-site research
  - Accessing health data for research purposes
HR 6: FDA Provisions

- Patient Focused Drug Development
- Qualification and Use of Drug Development tools (biomarkers)
- FDA Advancement of Precision Medicine
- Modern Trial Design and Evidence Development
- Expediting Patient Access
HR 6: FDA Provisions

- Incentivizes antimicrobial and antifungal development
- Incentivizes Vaccine development
- Streamlined data review
- Post market (Phase IV) studies to shift “off-label” to “on-label” uses
- Develop industry standards on ‘expanded access’ aka ‘compassionate use’
HR 6: Data Interoperability

We're stuck on an interoperable definition of interoperability
HR 6: Data Interoperability

- **Title I, Part 4**
  - HIPAA protections/disclosure improved
  - HITECH amendments, 45 CFR

- **Title II, Subtitle O**
  - FDA provisions for clinical trials with potential NIH impact
    (IRBs for devices, waivers of consent for clinical investigations)
  - Harmonize human subject protection guidance between HHS and FDA

- **Title III, Subtitle A**
  - ‘Ensuring Interoperability of Health Information Technology’
HR 6, 21st Century Cures
HELP’s “Healthy Americans”