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21st Century Cures, HR 6

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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

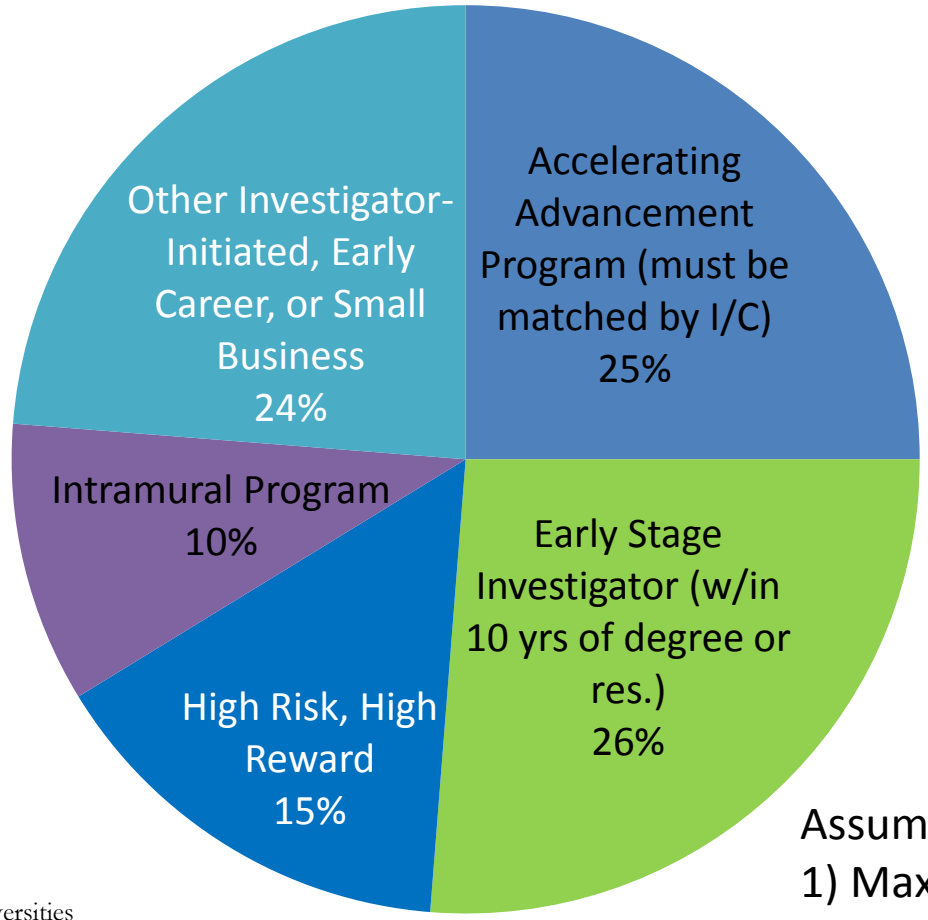
- NIH Innovation Fund
- NIH Strategic Plan
- Increased Accountability
  - I/C Director review of all research grant awards
  - IOM Study on Duplication in Biomedical research
  - Increase minority enrollment in studies and trials
  - Consider suggestions of regulatory burden groups

HR 6, 21st Century Cures

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



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 heath data for research purposes

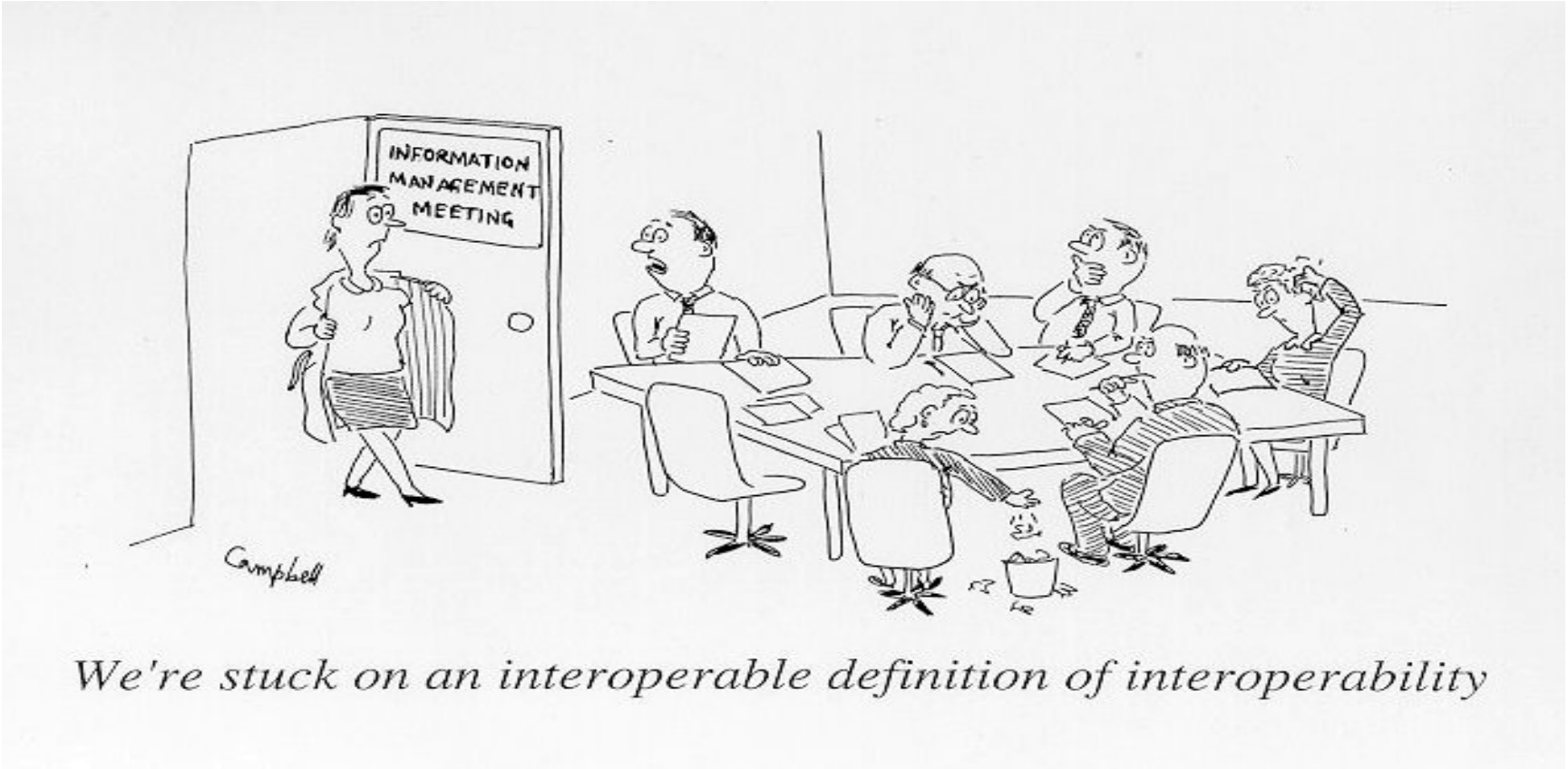
HR 6: FDA Provisions

- 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"