IRB Member Training
January 2017

H.R. 34: 21 Century Cures Act

“To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes"
What is it?

◊ Bi-partisan bill that President Obama signed into law 12/13/2016.
◊ Provides roughly $6.3 billion to fund new/existing research programs and creates accelerated mechanisms for the FDA to approve drugs and medical devices
◊ Boosts funding for mental health research and treatment, with hundreds of millions of dollars authorized for dozens of existing and new programs.
◊ $4.8 billion of this goes to the NIH to fund key Obama research initiatives (Cancer Moonshot, Precision Medicine Initiative, BRAIN initiative )
◊ Provides $500 million to the Food and Drug Administration (FDA) over 10 years to implement provisions in Title III to move drugs and medical devices to patients more quickly, while maintaining the same standard for safety and effectiveness
◊ More than 1,455 lobbyists representing 400 companies, universities and other organizations have lobbied for or against this bill since it’s initial conception in 2015 contributing more than half a billion dollars in the process.
◊ Provides $1 billion over 2 years for grants to states to supplement opioid abuse prevention and treatment activities. (ASAM reported roughly 55,403 lethal drug overdoses in 2015.)
Political Rationale

- Passed the House of Representatives in 2015 however stalled in the Senate shortly after and party lines were drawn. Republicans demanded regulatory rollback at the FDA and a clear way to fund it while Democrats wanted more funding for the NIH and prevention/treatment programs.

- Vice President Joe Biden became a major force for this bill as it provides funding for the Cancer Moonshot Program (Joe lost his son Beau to brain cancer 2015).

- Fred Upton, (R-Mich.) and Rep. Diana DeGette’s (D-Colo.), along with Director Francis Collins of the NIH, have been traveling the country with other lawmakers in an attempt to sell the project directly to the public and garner support for it.

- Fred Upton - who first conceived the 996 page bill - has received more than half a million in campaign contributions from big pharma/device manufactures since he created this bill in 2015.

- Mitch McConnell (R-Kentucky) – initially rejected the bill when it came to the Senate in 2015. Agreed to it after a adding a pro-regenerative medicine policy. (Ed Bosarge, who owns a company that provides regenerative therapies has donated roughly $2 million to a super PAC for Mitch McConnell since 2015.)
SEC. 3023. Protection of Human Research Subjects (the IRB stuff)

◊ Requires the Secretary of HHS to harmonize differences between the human subject regulations under the Common Rule and the Federal Food Drug and Cosmetic Act. Also attempts to streamline the institutional review board process for trials that are being conducted at multiple sites.

- Minimize instances of regulatory duplication and unnecessary delays
- Align with current practices in the context of multisite and cooperative research projects
- Facilitate the use of collaboration and shared review and oversight pathways among entities engaged in human subjects research
- Protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs
- Ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may: use joint or shared review, rely upon the review of an independent IRB and/or an IRB of an entity other than the sponsor of the research
- No later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization
5 Changes to the FDA

- Requires FDA to evaluate the use of real world evidence to help support the approval of a new indication for a previously approved drug and to help support or satisfy post-approval study requirements. (Sec. 3022. Real World Evidence)

- Establishes a review pathway at FDA for biomarkers and other drug development tools that can be used to help shorten drug development time and reduce the failure rate in drug development. (Sec. 3011. Qualification of Drug Development Tools.)

- Requires the FDA to include a statement regarding any patient experience data that was used at the time a drug is approved. Patient experience data includes data collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturer) (Sec. 3001. Patient Experience Data.)

- Allows sponsors of genetically targeted or variant protein targeted drugs to rely on data for the same or similar technology from previously approved applications by the same sponsor (Sec 3012 Targeted Drugs for Rare Diseases.)

- Allows FDA to rely upon qualified data summaries to support the approval of an application for a new indication of an already approved drug. (Sec. 3031. Summary Level Review.)
More IRB Related Changes

- Provides FDA the flexibility to waive or alter informed consent requirements for clinical trials with minimal risk, similar to existing flexibility for HHS and NIH under the Common Rule. *(Sec. 3024. Informed Consent Waiver or Alteration for Clinical Investigations.)*

- Strikes the requirement that a sponsor of a medical device trial always use a local institutional review board. This change will allow the use of centralized models. *(Sec. 3056. Institutional Review Board Flexibility.)*

- Allows the Director of the NIH to require grant recipients to share the data that is generated from the NIH-funded research. *(Sec. 2014. Data Sharing.)*

- Establishes authority for the HHS Office of the Inspector General to investigate claims of information blocking and assign penalties for practices found to be interfering with the lawful sharing of EHRs. *(Sec. 4004. Information Blocking.)*

- Improves the regulation of combination products – products that contain both a drug and device, for example – by requiring that FDA meet with sponsors and agree early in development how to best study the combination product to meet the standard for approval. *(Sec. 3038. Combination Product Innovation.)*
Changes in HIPAA

✧ The Sense of Congress finds that clarification is needed regarding existing permitted uses and disclosures of health information under the Health Information Portability and Accountability Act (HIPAA) by health care professionals to communicate with caregivers of adults with SMI to facilitate treatment (Sec. 1101 – Sense of Congress)

✧ Requires the Secretary to, within a year of finalizing updated rules related to the confidentiality of health records related to alcohol and drug abuse, convene relevant stakeholders to determine the effect of the regulation on patient care, health outcomes, and patient privacy (Sec. 11002. Confidentiality of Record)

✧ Directs the Secretary through the Director of the Office for Civil rights to clarify circumstances when a health care provider or covered entity may use or disclosure protected health information related to the treatment of an adult with a mental or substance use disorder. (Sec. 11003. Clarification on Permitted Uses and Disclosures of Protected Health Information)

✧ Requires the Secretary to identify or recognize private or public entities to develop model training and educational programs to educate health care providers, regulatory compliance staff, and others regarding the permitted use and disclosure of health information under HIPAA. (Sec. 11004. Development and Dissemination of Model Training Programs)
Critics

- **Elizabeth Warren (D-Mass)** “I cannot vote for this bill, I will fight it because I know the difference between compromise and extortion. Congress shouldn't be in the business of selling FDA favors to the highest bidder, risking people's lives to enrich political donors”

- **Bernie Sanders (D-Maine)** “At a time when Americans pay, by far, the highest prices in the world for prescription drugs, this bill provides absolutely no relief for soaring drug prices. The greed of the pharmaceutical industry has no limit, and this bill includes numerous corporate giveaways that will make drug companies even richer.”

- **The National Physicians Alliance** “Rather than addressing the true scientific bottleneck in drug and device development, the bill includes unnecessary, costly, and potentially harmful regulatory changes and financial incentive for pharmaceutical and medical device companies that would put patient safety at risk and undermine public health.”
Controversial Topics

- Funding isn’t guaranteed, it will have to be appropriated each year by Congress as part of their annual budget negotiations
  - More than $3 billion for funding comes from Obamacare's Prevention and Public Health Fund and Medicaid
- Doesn't include provisions to rein in prescription drug prices (price gauging recently ex: epipen and Turing Pharmaceutical's Daraprim)
- “Real World Evidence” vs Clinical Trials? Treatment of disease vs Prevention of disease?
- Drug manufactures can use surrogate biomarkers/endpoints as point of evidence for why a drug/device needs to get approved
- The FDA already is the fastest regulatory drug approval body in the world
- Lobbyists role in passage of this bill: Drug Approval over Safety of Patients
  - The Pharmaceutical Researchers and Manufacturers of America, or PhRMA, spent over $30.3 million
  - AbbVie, the maker of Humira, spent around $9.5 million
Points for Discussion

 chave How do IRBs minimize regulatory duplications while considering the local needs of the community?
 chave In light of these changes, how should IRBs adapt moving forward?
   chave As efforts are made to modernize clinical trials, how do IRBs determine that risks are appropriately minimized?
   chave Will patient experience data change how IRBs assess risk?
   chave Do we need to change the way we talk about clinical trials during the informed consent process?
   chave How do IRBs minimize regulatory duplications while considering the local needs of the community?
   chave How do you define “least burdensome” as it relates to subject safety?