Science: The intellectual and practical activity encompassing the systematic study of the structure and behavior of the physical and natural world through observation and experiment.

Regulatory: To control or direct according to rule, principle, or law.
Regulatory Science: The intellectual and practical activity encompassing the systematic study of the structure and behavior of the regulatory world through observation and experiment to determine the impact of the rules, principles and laws governing FDA regulated research.
Regulatory Review from a Scientific Perspective (1)

- **Introduction** - What was the original purpose of the regulation?
  - Generation of the hypothesis to be tested.

- **Methods/Results** - Impact of the regulation
  - How successful has the regulation been in achieving the original purpose?
  - Have there been any unintended (often unanticipated) consequences?
Regulatory Review from a Scientific Perspective (2)

- Methods/Results (2) - Impact of the regulation
  - What has been the cost (broadly defined) of the implementation of the regulation?
- Discussion – What is the overall value of the regulation?
- Conclusion – The regulation should be modified, eliminated or left unchanged.
Examples of a Law and a Regulation Amendable to Scientific Study

- Food and Drug Administration Amendments Act of 2007 – Title VIII (Expansion of ClinicalTrials.gov [CT.gov])
  - Purpose: “To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials.”

- Title 21, Chapter 1, Subchapter D, Part 314, Subpart I--Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible (2-Animal Rule)
Core Competencies Helpful in Addressing these Questions

- Legal
- Surveying
- Metrics
- Systems Analysis
- Government
- Economics
- Communication
- IRB Experience
- Clinical Research Operations
- Technology Transfer
- Information Technology
- Bioethics
Example #1: Food and Drug Administration Amendments Act of 2007 – Title VIII

- **Purpose:** “To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials.”

- **Hypothesis:** The expansion of CT.gov to include a results database has enhanced patient enrollment and provided a way to track progress of clinical trials without generating excessive “costs”.
Example #1 (con’t):  Food and Drug Administration Amendments Act of 2007 – Title VIII

- Methods/Results: Compare rates of enrollment by several metrics (total number of patients in clinical studies; percent of studies filled within specified timeframe); Survey literature for papers utilizing data from CT.gov; RFI for public input; utilization of website; quantify impact of additional regulation [new informed consent language, additional staff].
Example #2: Two-animal Rule

- Purpose: To enable the licensure of products that have been studied for their safety and efficacy in ameliorating or preventing serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substances and for which: Definitive human efficacy studies cannot be conducted because it would be unethical to deliberately expose healthy human volunteers; and field trials have not been feasible.
Example #2: Two-animal Rule

- **Hypothesis:** Products in this category that would have not been able to be licensed have been licensed.

- **Methods/Results:** Identify potential products that fall into that category and assess the impact of the regulation on their ability to be licensed.