Regulate or Innovate: Can We Do Both?

STA-FAER Joint Panel
STA 2013 Annual Meeting
January 10, 2013
Phoenix, AZ
Anesthesia Conference on Innovation and Entrepreneurism

- One-day meeting on January 18, 2014
- Held in conjunction with 2014 STA meeting
- Panel and workshop topics:
  - Protecting intellectual property
  - Developing entry and exit strategies for funding IP
  - Understanding regulatory pathways
PANELISTS

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Jeffrey M. Feldman, MD, MSE (Moderator)
Professor of Clinical Anesthesiology
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What is Innovation?

The commercially successful application of a new idea.

- Joseph Schumpeter (economist)
Strange Bedfellows


JM Feldman STA 2013
Medical Device Regulation History

- 1906: Pure Food and Drug Act (origins of the FDA)
  - Regulated interstate commerce of adulterated or misbranded drugs
- 1938: Federal Food Drug and Cosmetic Act
  - Established safety as a criteria for approval
  - Distinguished devices from drugs
- 1962: Kefauver – Harris Amendments
  - Required proof of efficacy & greatly expanded the scope and cost of the PMA process for drugs NOT medical devices
- 1976: Medical Device Amendments
  - Established Pre-market Approval Process for Devices
- 1982: Center for Devices and Radiologic Health (CDRH)
  - Combined Separate Bureaus
- 1990: Safe Medical Devices Act
  - Reporting of incidents related to death or serious illness/injury
FDA Innovation Pathway

- Recognized the need to manage costs and time commitment for medical device approval process

- Goals
  - Shorten time to develop safe and effective products
  - Pre-submission Collaboration with Developers
  - Maintain standards for showing safety and effectiveness

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/ucm283511.htm
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Medical Device Amendments (1976)

- Established pre-market approval process for devices distinct from drugs
- Classified devices into three categories
  - Impact on human health
  - Potential for injury
- Class 3 devices
  - Support or sustain life or present an unreasonable risk of injury.
  - Require pre-market notification and approval
    » Similar to drugs where safety and efficacy must be demonstrated in controlled studies
  - Can be marketed immediately if proven to be substantially equivalent to pre-1976 devices
Medical Devices & Innovation

- Impact of current regulatory approach on Medical Device Innovation

- Commercial viability
  - Market opportunity generally does not support PMA process
  - Requires substantial equivalence (510K)
    - Incremental Innovation possible
    - Radical Innovation difficult

- Is radical innovation desirable?
  - Streamline regulatory process to foster innovation
FDA References

➢ End Stage Renal Disease Pilot
  – 3/32 Applicants selected
    » iRAD: Implantable renal assist device
    » WAK: Wearable Artificial Kidney
    » HVS: Hemoaccess Valve System
  – http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/ucm286140.htm

➢ Innovation at the FDA
  – http://www.youtube.com/watch?v=hBm-wDrmg6U