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)
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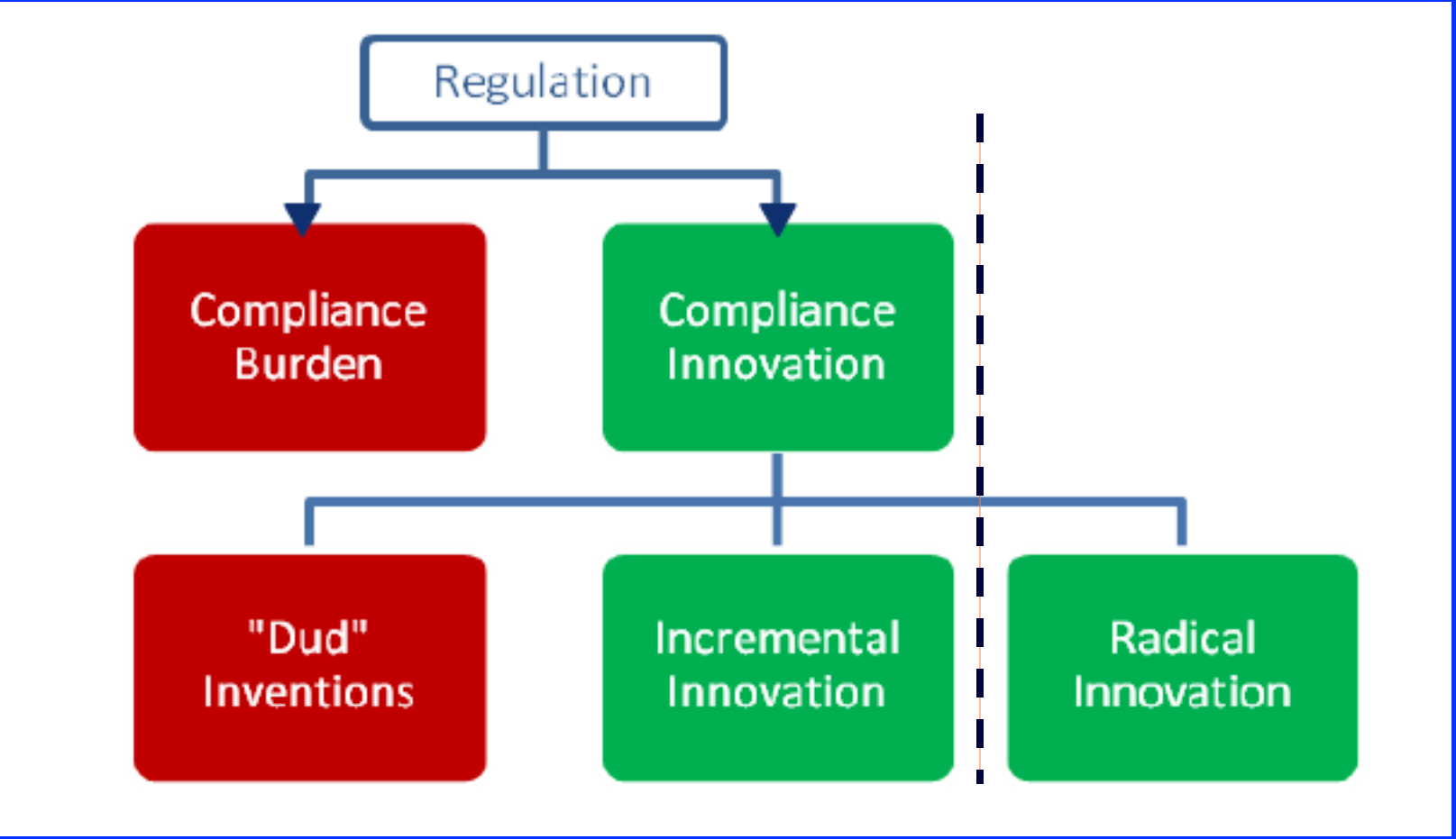
What is Innovation?

The commercially successful application of a new idea.

- Joseph Schumpeter (economist)

Strange Bedfellows



Ref: Stewart LA. The Impact of Regulation on Innovation in the United States: A Cross-Industry Literature Review. Information Technology & Innovation Foundation, June 2010.

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 Consumer Magazine, Jan-Feb, 2006.

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