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Regulatory Challenges for the Wireless Health Industry

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Good News & Bad News

- Good News
  - FDA stating in their strategic plan “mission critical” areas of applied research – wireless healthcare devices
  - The Council on Medical Device Innovation - identified areas of unmet public health need that could be addressed with medical products. The five areas identified in 2010 included two settings, wireless health care and home use of devices, and three medical targets, diabetes, spinal cord injury, and cancer.
  - FDA and FCC are working together to bring forward innovative wireless technologies for healthcare faster
  - Patents covering wireless aspects of medical technology are growing at a much faster rate than other device patents and make up 31% of the total.

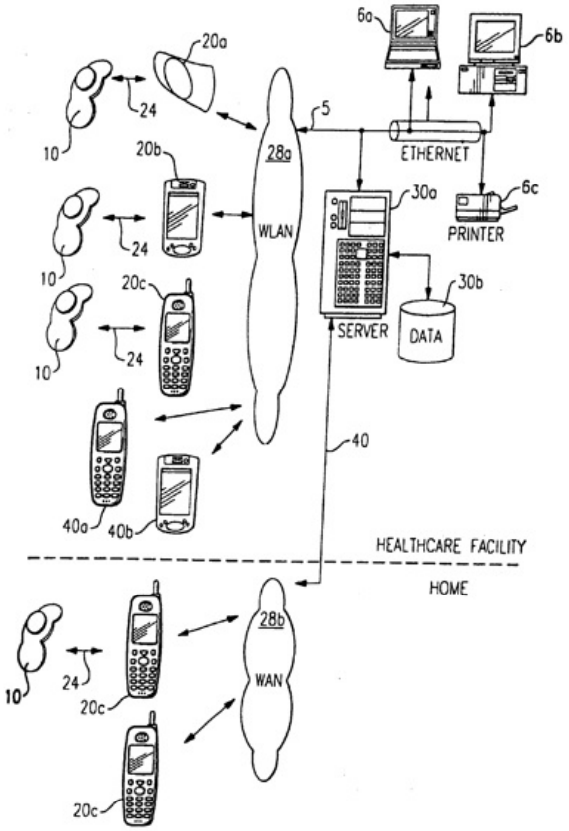

FIG.2

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Good News & Bad News

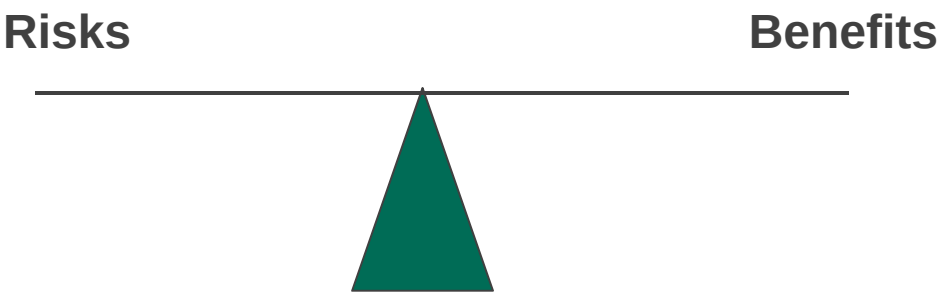
- Bad News
  - Cutting edge wireless devices may be so novel that there may be no prior similar device(s) to base your approval pathway on
  - The level of evidence FDA wants for wireless devices is higher since they believe wireless is inherently less reliable than wired communication
  - Wireless Monitors: FDA believes diagnostic data is dangerous! They want to know: What are you monitoring/measuring, how often, and most importantly what will the user do with the information?
    - You must prove that the information being provided will not be mis-used (i.e., leads to inappropriate actions) and that it provides clinical benefit
  - Therapeutic devices: The bar is even higher

FDA Paradigm for Diagnostic Devices

- Relies heavily on intended use and claims being sought
  - ➢ "Functional" (e.g., "measures temperature") – Inaccurate information causes small risk to patients…

    …can be counterbalanced by small benefits
  - ➢ "Diagnostic" (e.g., predicts rupture risk") – Misdiagnosis causes greater risk to patients…

    …needs to be counterbalanced by large benefit



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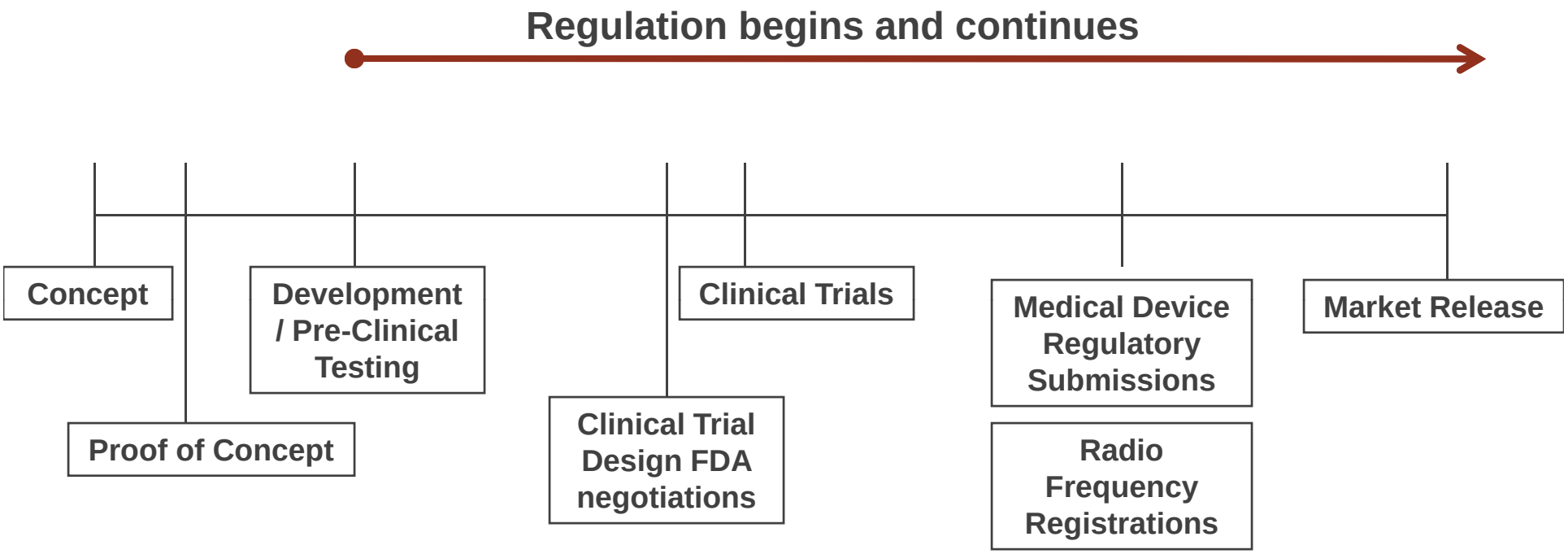
New Medical Technology Development Lifecycle



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Typical Types of Product Pre-Clinical Testing

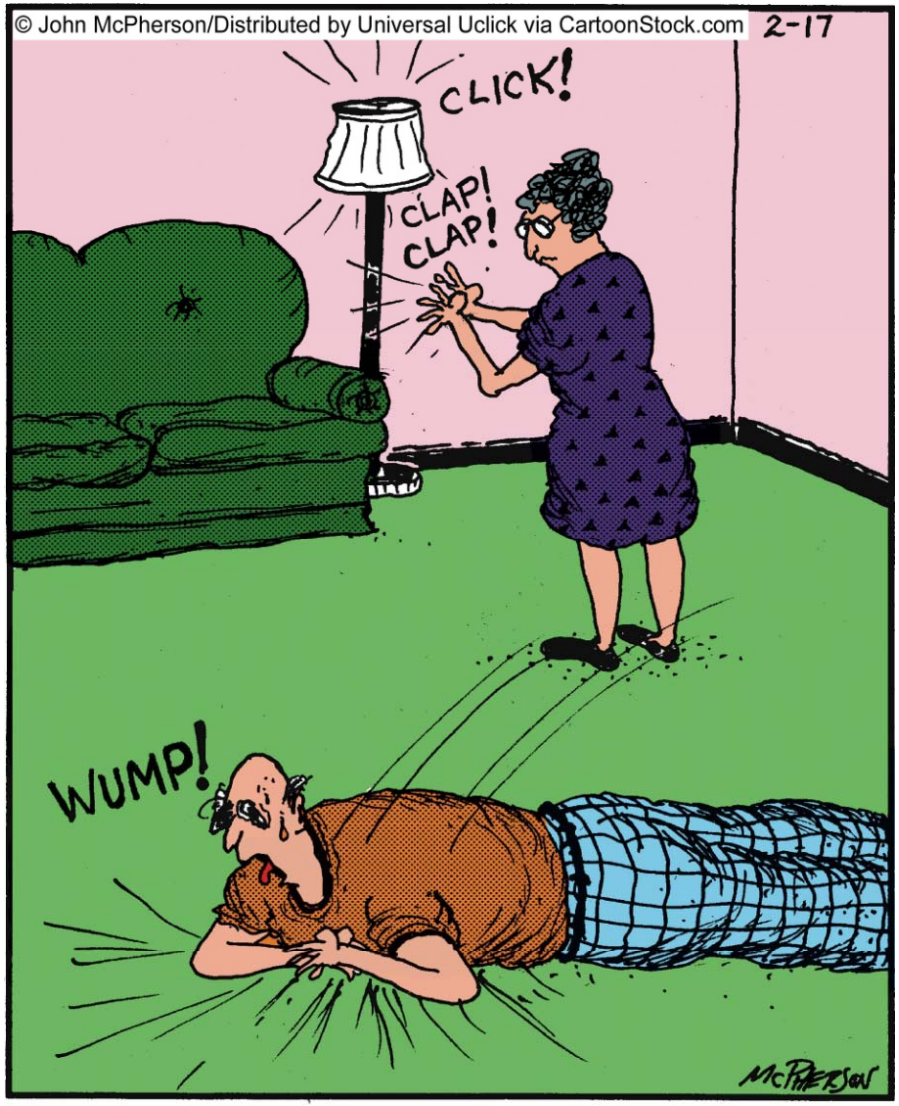
- Component verification
- Electrical parameter testing
- Software validation
- System integration testing
- Environmental testing
- Electromagnetic compatibility testing
- Biocompatibility testing
- Packaging verification
- Sterilization validation
- Human factors/usability testing
- Animal studies

Unique Wireless Design Challenges

- Beyond standard safety & effectiveness considerations, FDA has additional concerns for wireless devices, including:
  - Wireless coexistence
  - Wireless Performance
  - Data Integrity
  - Security
  - Electromagnetic compatibility (EMC)
- Since these issues affect all stages of the product life cycle, FDA recommends they be considered in:
  - design requirements
  - design verification and validation
  - risk management processes and procedures

Design Challenges

- **Wireless reliability of communication**
  - Connections lost without warning, failure to establish connections, or even slight degradation of service/signal can have serious consequences.
  - FDA especially concerned for devices having:
    - wireless transmission of critical medical device alarms
    - continuous physiological waveform data
    - real-time control of therapeutic medical devices (such as wireless footswitches)
    - time-critical medical telemetry (such as for real-time patient waveforms and alarms)
    - wireless control of therapeutic devices.



Claire discovers that The Clapper operates on the same frequency as Don's pacemaker.

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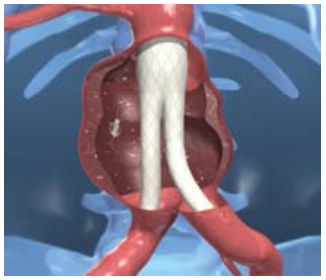
Radio Frequency Device Registration Challenges

- Requirements differ between countries: less harmonization
  - Some countries accept testing performed for US/FCC and Europe/ETSI EN
  - Some require additional ”in-country” testing and certification
  - Some require model specific certification
  - Some require RF approval prior to medical device registration, others accept parallel paths

- Each region has-
  - different design update handling procedures
  - different user’s manual and labeling requirements for country specific symbols and warnings
  - Varying approval times for Telecommunications Authority approvals, from a few weeks up to 4 months

Wireless Implantable Monitor Examples

- CardioMems Abdominal Aortic Anerysm (AAA) sensor
  - Intended for measuring intrasac pressure during and upon completion of endovascular procedures
  - 510(k) cleared with no human clinical studies



- Pulmonary Artery Pressure (PAP) Sensor[1]
  - Same sensor as above placed in different location
  - Intended use – Reduce heart failure hospitalizations by measuring PAP
  - Original PMA, 500+ patient IDE human clinical trial to establish safety (adverse events) and effectiveness (reduction in heart failure hospitalizations)

[1]***CAUTION*** *- Investigational device. Limited by federal law to investigational use.*

Regulatory Strategies

- Do your homework – find out what other products are approved/cleared that you can leverage as examples or predicates (FDA website, company websites, medical journals, clinicaltrials.gov, etc.)
- Design and test to internationally recognized standards whenever possible
- Talk to FDA early and often to propose indications for use and pre-clinical test strategies and to determine regulatory path [510(k), IDE, PMA]
- Build in time in the schedule to negotiate the clinical trial design and endpoints with FDA
- Consider OUS human feasibility studies

Regulatory Strategies (cont.)

- Plan for EU market release (CE Mark) first
- Consider going to market first with a simple application of the technology or limited intended use (e.g., discrete measurements in a healthcare setting versus continuous monitoring at home).
  - ➢ Benefits
    - Get to market faster
    - Generate revenue sooner
    - Gain clinical/user experience before proceeding with more complex or higher risk applications
    - Build relationship and trust while educating the regulatory agencies on the technology

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Thank You

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