FDA Medical Device Policy: A Look into the Future

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CDRH Vision

Patient-Centric Vision

- Patient Access to:
  - High quality
  - Safe and effective Medical devices
    - of public health importance
  - First in the world (as quickly as possible)
Promote and protect the public health
- Promote = adapt behaviors to accelerate regulatory approval
- Protect = ensure devices are safe and effective
- Strike the right balance

CDRH Director Shuren acknowledges
- Current construct emphasizes "protect"
- CDRH needs to do more to "promote"
  - Well recognized US is lagging behind the EU
  - Can be done without sacrificing protect mode
Facilitate medical device innovation
  – Advance regulatory science
  – Provide industry with
    • Predictable
    • Consistent
    • Transparent
    • Efficient regulatory pathways
  – Assure consumer confidence in devices here in the US
Strengthen the clinical trial enterprise
Strike the right balance between pre-market and post-market data collection
Provide excellent customer service
Strengthen the Clinical Trial Enterprise (to promote the public health)
  – Incent manufacturers to choose the US over the EU
    • Address concerns about time and cost to meet FDA standard
Steps taken to date:
  – Pilot program guidance to facilitate early clinical evaluation of novel device technologies, using risk mitigation strategies to appropriately protect human subjects
  – 2013 draft guidance issued on FDA decisions for IDEs
  – Medical Device Innovation Consortium's Clinical Trial Innovation and Reform Project
Goals to Strengthen the Clinical Trial Enterprise

- Improve efficiency, consistency, and predictability of IDE process
  - Reduce time and number of cycles to obtain full IDE approval
- Increase the number of early feasibility/first-in-human IDE studies conducted in the US
Strike the Right Balance Between Pre-market and Post-market Data Collection

- Recognize we cannot know all answers before going to market
- All medical devices have a risk profile - it cannot be eliminated
- Shift to post-market where appropriate
- CDRH goal - review all PMA device types by December 31, 2015 to identify those eligible for post market data shift or down classification
  - Review 50% by December 31, 2014
  - Review 75% by June 30, 2015
Strike the Right Balance Between Pre-market and Post-market Data Collection

- Draft Guidance Issued April 23, 2014 -- Comments Due July 22, 2014
  - Apply the least burdensome standard
  - probable health benefit v. probable risk of injury or illness
  - devices eligible for the post-market data shift
    - mature technology with well-documented benefits & risks
    - incorporating measures capable of mitigating known risks
    - modify warning labels, contraindications, precautions
    - previously well-studied in high risk population - now study in low risk population
    - intended for long-term use when long-terms risks unknown
    - known to have rare adverse events
    - capable of being approved based on bench data with post-market confirmatory clinical data
Provide Excellent Customer Service

- For all stakeholders
  - Patients
  - Industry
  - Health care professionals
- Understanding and addressing stakeholder needs
  - Active listening
  - Problem solving
  - Seek out ideas from others
  - Clear communications
  - Learn from mistakes
Provide Excellent Customer Service

- Draft EAP Guidance -- Issued April 23, 2014 -- Comments Due July 22, 2014
  - Voluntary program
  - Collaborate early and often to determine data collection needs
    - Data Development Plan balances pre & post-market needs
  - For devices that demonstrate potential to address unmet medical need for life threatening or irreversibly debilitating diseases
    - Breakthrough technology that provides clinically meaningful advantage over existing technology
    - No approved alternative treatment or means of diagnosis exists
    - Availability of the device is in the best interest of patients
Provide Excellent Customer Service

- The 510(k) Modification Story - A Case Study in Customer Relations
  - Define Your Customer: patients, industry, Congress
  - Define the Problem to be Solved
  - July 9, 2012: Section 604 of FDASIA reinstates 1997 Guidance
  - January 7, 2014: FDA Report to Congress
    - 1997 Guidance provides solid foundation
      - Keep the decision trees!
      - Explain key regulatory terms
      - Clarify process to determine a manufacturer's regulatory obligation vis-à-vis a modified device
    - Leverage QSRs
Thank You!

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