Device Regulation -- Past, Present, and Future

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Agenda

- A brief history of FDA regulation
- Theory of regulation
- Overview of FDA device regulation
- OUS device regulation
- Current FDA issues
- Future trends in device regulation
FDA is not the only regulatory agency impacting medical devices

- SEC
- OSHA
- FTC
- FCC
- OUS country regulations
- Etc.
A Brief FDA History

- **1906 Pure Food & Drug Act**
  - Required food and drugs to not be adulterated or misbranded. Triggered by meat packing conditions documented in “The Jungle”

- **1938 Food, Drug, and Cosmetic Act**
  - Required FDA approval for drug safety. Triggered by Elixir Sulfanilamide deaths due to diethylene glycol toxicity

- **1962 Drug Amendments**
  - Increased Drug safety standard and required demonstration of effectiveness. Triggered by birth defects caused by Thalidomide.

- **1976 Device Amendments**
  - Established premarket requirements for medical devices. Triggered by Dalkon Shield IUD injuries
A Brief FDA History (cont.)

- **1990 Safe Medical Devices Act (SMDA)**
  - Established authority for Design Controls, Tracking, Postmarket Surveillance, Corrections and Removals reporting, and specific Penalties for non-compliance

- **1997 FDA Modernization Act (FDAMA)**
  - Numerous changes intended to accelerate device approvals and reduce device approval “gap”
  - Established 30-day notice for certain manufacturing changes

- **2002 Medical Device User Fee and Modernization Act (MDUFMA)**
  - Established Device User Fees

- **2007 MDUFMA II**
  - Reauthorized Device User Fees.
Theory of regulation

- Society expects central government to help keep them safe (e.g., Steamboat Boiler Act of 1838)
- Safety is the second step (after physiological needs met) in Maslow’s hierarchy
- Typically results in a generalized solution in reaction to a specific problem
- When in doubt, regulate. GAO never finds fault in overregulation!
Regulation Begets Regulation

- Resources grow with time
- Activity finds other “problems”
- More regulation develops
- Opportunities for action abound!
FDA Is A Political Not A Scientific Agency

- Part of the executive branch
- Overseen by legislative and judicial branches
- Responds to public and political pressure (e.g., Plan B)
- Reactive to problems
- “A slow moving target that bleeds profusely when hit.”
Main FDA Device Regulations

- 21 CFR (Code of Federal Regulations)
  - Part 801 (Labeling)
  - Part 803 (Medical Device Reporting)
  - Part 806 (Corrections and Removals)
  - Part 807 (Registration, Listing, Premarket Notification (510k))
  - Part 812 (Investigational Device Exemption)
  - Part 814 (PreMarket Approval)
  - Part 820 (Quality Systems)
  - Part 821 (Device Tracking)
  - Part 822 (Postmarket Surveillance)
  - Part 860 (Device Classification)

- Parts 210/211 (Drug cGMP)
FDA Submission types

- PreMarket Approval (PMA)
- 180-day PMA-Supplement
- Real-Time Review PMA-Supplement
- 30/135-day Notice
- Investigational Device Exemption (IDE)
- IDE-S
- 510k
- PMA Annual Report
FDA PMA approval standard

- “… valid scientific evidence … there is reasonable assurance that the device is safe and effective…”

- “Valid scientific evidence is evidence from well-controlled investigations … that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use…”
User Fees

- User fees for medical devices updated in 2007 by MDUFMA II.
- Current fees (FDA FY08):
  - PMA ----------- $185,000
  - PMA-S -------- $27,750
  - RTR PMA-S - $12,950
  - 510K --------- $3404
  - New fees for 30-day notice, reclassification petition, facility registration, PMA Annual report
- ~23% of CDRH budget in FY08
- Some improvement in performance goal incentives
- Overall approval times not improved
- FDA challenge to also find resources to support increased postmarket surveillance
OUS Device regulation examples

- European Community
  - Single Notified Body approval allows distribution throughout EC
  - Notified Bodies (e.g., TUV) are private companies overseen by government Competent Authorities
  - Conformance to Directive (safety) presumed if compliant to harmonized standards
  - Lower standard of effectiveness than US
  - Requires license renewal every 3-5 years to continue distribution
OUS Device Regulation Examples

- Japan
  - Significant changes to Pharmaceutical Affairs Law (PAL) in 2005
  - Reviews performed by PMDA, a quasi-governmental agency overseen by MHLW
  - Very prescriptive submission requirements and very detail oriented review
  - Very low tolerance for quality issues
How FDA ensures compliance

- Review of manufacturer S & E data prior to marketing (e.g., PMA)
- Review of manufacturer postmarket information
  - MDR
  - C&R reports
  - Postmarket studies
- Facility Inspections
- 483/Warning Letters
- Civil/Criminal penalties
Is FDA a burden on industry?

- Generally requirements reflect good business/science (there are exceptions!)
- FDA regulation provides barrier to entry for potential competitors
- Helps ensure market confidence and credibility with physicians, patients, and public (currently an issue!)
- The capability to comply with FDA regulations may be a competitive advantage
Recent FDA Postmarket Issues

- Products
  - ICDs
  - DES
  - Vioxx

- Process
  - MDR review/MAUDE database
  - PMA Annual report content/review
  - COA/522 postmarket studies
  - Lack of FDA cross division communication
  - Product change notification/approval
Future trends in device regulation

- Increased regulator to regulator communication
- Global Harmonization for device approvals?
- Focus on Supplier Controls part of QSR
- Increased focus on postmarket performance
- FDA user fees?
- More targeted approach to inspections
- Increased evidence required for device approval
- Increased device regulation in emerging markets (e.g., China, Korea, India)
Questions?