FDA Regulation of Medical Devices
Postmarket Requirements

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Recall from Last Week...

- Premarket Requirements
  - Product Classification – Type I, II or III
  - Premarket Approval (PMA)
    - PMA Supplements
    - Evaluations of the PMA and PMA Supplement Process
    - Humanitarian Device Exemption (HDE)
  - 510(k) Notification – Substantially Equivalent Device
    - Traditional 510k
    - Abbreviated 510k
    - Special 510k
    - De Novo 510k

Postmarket Requirements

- Postmarketing Surveillance and the National Evaluation System for Health Technology (NEST)
  - Postmarket Surveillance Studies ("522 Studies")
  - Adverse Event Reporting
  - Medical Device Tracking
  - The Sentinel Initiative
  - Unique Device Identification (UDI) System

Johnson, J. A., FDA Regulation of Medical Devices, 2016
Postmarket Surveillance Studies

- Monitors the on-going safety.
- Corrective actions
  - Changing the device labeling.
  - Changing the instructions for use.
  - Improving user training.
  - Removal of the device from the market if appropriate.
- Issues
  - Some foreign surveillance systems have identified serious device safety concerns sooner than in the United States.
- Additional Benefit
  - Understanding and measuring device innovation and cost-effectiveness

Information sources:
- Medical Device Reporting (MDR).
  - Adverse Event Reporting within 30 Days by manufacturer.
  - Annually hundreds of thousands of reports of confirmed or possible medical device related malfunctions, serious injuries, and deaths.
  - Network of 280 US hospitals ~5,000 reports annually.
- Post-Approval Studies
  - May be a condition of PMA approval.

- 522 Postmarket Surveillance Studies (Class II and III Devices).
  - If failure may cause serious consequences.
  - If intended for significant use in pediatrics.
  - Intended to be implanted >1 year.
  - Life-supporting or sustaining outside a device user facility.
- FDA Discretionary Studies.
  - FDA conducts its own research
    - Use of privacy-protected data- National registry, Medicare & Medicaid, EHR and literature.
- National Evaluation System for health Technology (NEST)
- Real World Data (RWD)
  - Data collected outside of traditional clinical trials.
Medical Device Tracking

- FDA may issue a **tracking order** for any Class II or Class III device if:
  - If failure may cause serious consequences
  - Intended to be implanted <1 year
  - Life-supporting or sustaining outside a device user facility.

The Sentinel Initiative

- Launched in 2008
- **Postmarket risk identification system**
  - Monitoring all FDA regulated products – drugs and medical devices after they have reached the market.
  - As of 2012 there was secure access to data from ~126 million patients.
  - Health partners: academic medical centers, healthcare systems and health insurance companies.

*National Medical Device Evaluation System...*
Table 1: Objectives of the NMDES Coordinating Center

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<tr>
<th>Objective</th>
<th>Description</th>
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<td>Ensure a means to expand, quality, and enhance the evaluation of medical devices</td>
<td>The Coordinating Center provides an efficient and comprehensive means of reviewing and reviewing the evaluation of medical devices. A quality assured, validated data collection and review program is established. The Coordinating Center also provides an evidence-based, efficient and comprehensive means of reviewing the evaluation of medical devices.</td>
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<td>Promote the adoption of new practices for device evaluation</td>
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<td>Develop a transparent and coordinated process for evaluating and improving the safety and effectiveness of medical devices</td>
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<td>Develop a sustainable business model for a national medical device evaluation system</td>
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Other Requirements

- **Labeling:**
  - All labels and accompanying printed matter — including advertising.

- **Manufacturing**
  - Good Manufacturing Practice (GMP) (as described in the Quality System (QS) regulations)

- **Compliance and Enforcement**
  - Inspection
  - Warning Letter
  - Product Recall

Summary

- **Postmarket Requirements**
  - Postmarket Surveillance Studies.
  - Adverse Event Reporting, Medical Device Tracking, UDI (Unique Device ID)
  - National Medical Device Evaluation System.
  - Labeling and Manufacturing
  - Compliance and Enforcement