ENGELBERG CENTER for Health Care Reform at BROOKINGS

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Strengthening Our National System for Medical Device Postmarket Surveillance

Complementing Sentinel Efforts

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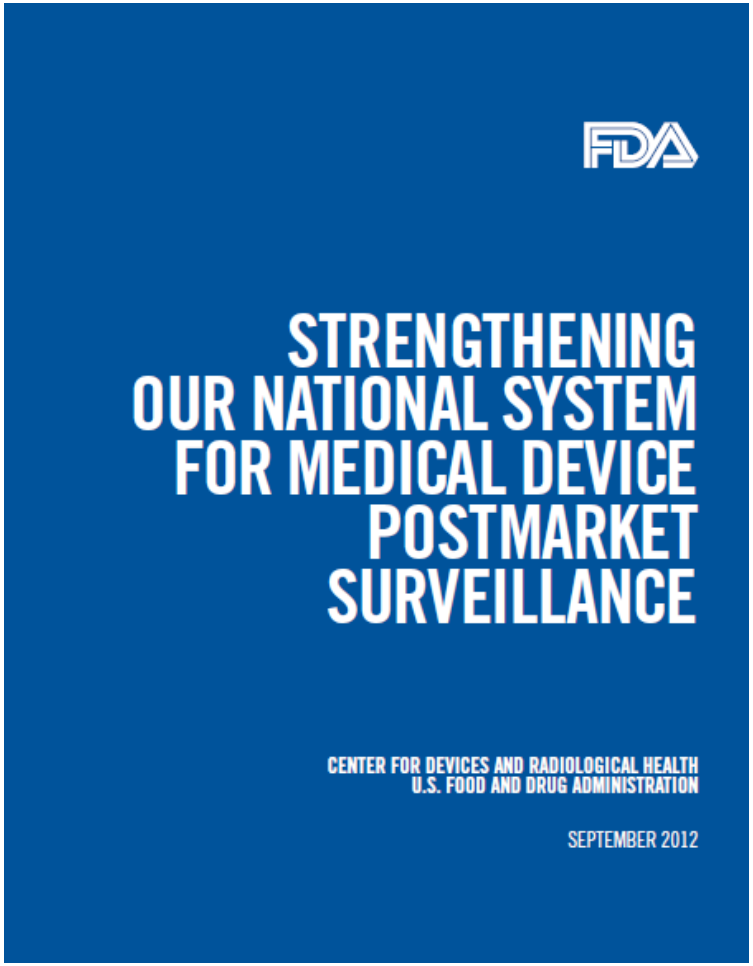
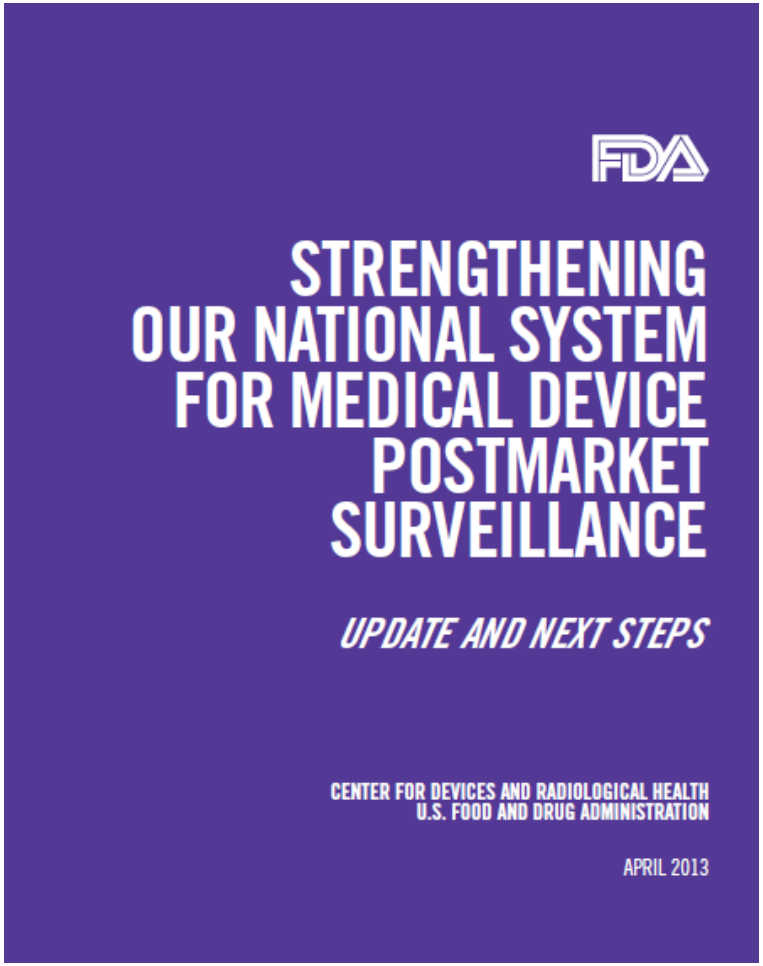
CDRH

Strengthening Our National System

Taking the Next Steps





National System: FDA's Vision

- Communicates timely, accurate, systematic, and prioritized assessments of devices throughout their marketed life using high quality, standardized, structured, electronic health-related data
- Identifies potential safety signals in near real-time from a variety of privacy-protected data sources
- Reduces the burdens and costs of medical device postmarket surveillance
- Facilitates the clearance and approval of new devices, or new uses of existing devices

Proposed Specific Actions to Strengthen Device Postmarket Surveillance

1) Establish a Unique Device Identification (UDI) System and Promote the Incorporation of UDI into Electronic Health Information (EHI)
2) Promote the Development of National and International Device Registries for Selected Products
3) Modernize Adverse Event Reporting and Analysis
4) Develop and Use New Methods for Evidence Generation, Synthesis, and Appraisal

Implementation Steps: UDI

- Final UDI rule issued (Sept. 2013)
- Global UDI database (GUDID) established (Sept. 2013)
- Facilitate incorporation of UDI into EHRs (2014+)
  - Provide requirements for EHR certification
  - Help craft a significant meaningful use objective(s)
  - Ensure UDI integration/coordination with HL7 messaging standards
  - Encourage creation of UDI use cases and implementation pilots
- Facilitate incorporation of UDI into claims (2014+)
  - Assess business cases and technical requirements (work hosted by Pew and Workgroup for Electronic Data Interchange)
- Develop “roadmap” for stakeholder-driven UDI implementation (work hosted by Brookings)

UDI Phased Implementation

9/24/2013

GUDID, UDI Website, and UDI Helpdesk Available

1 Year (9/2014)

Class III devices

2 Years (9/2015)

Implants and Life Supporting/Life Sustaining

3 Years (9/2016)

Class II devices

5 Years (9/2018)

Class I devices

Critical Role of Registries

- May provide manufacturer-specific identifiers
- Provides clinically rich information (about patient and procedure)
- May be longitudinal (if integrated with/linked to appropriate sources)
- Provides rate information on clinical outcomes
- **Fills critical void in absence of UDIs**

Implementation Steps: Registries

- Workgroup on Future Directions for Medical Device Registries (hosted by Pew, Blue Cross and Blue Shield, MDEpiNet) (2013)
  - Discussed key issues on development and use (e.g., registry burden, when to use device registries)
- Establish a Medical Device Registry Task Force of Key Stakeholders (hosted by MDEpiNet) (2014+)
  - Define governance and data quality practices to meet multi-stakeholder needs
  - Leverage on-going efforts
  - Develop strategies for the use of registries to support premarket approval and clearance

Challenging Device Characteristics

Considerations for Active Surveillance

- Heterogeneity (from genetic tests to heart valves)
- Complex components (software, hardware, biomaterials)
- Iterative changes (rapid evolution)
- Human factors (e.g., surgical technique)
- Learning curve

Device Participation in Sentinel

- Contributed to methods work group activities
- Provided input into exposure taxonomy, health outcomes of interest
- Provided input into anonymous linkage effort (between registry and claims)
- Submitted device queries
  - utilization of hip arthroplasty devices by articulating surface (by device group)
  - safety evaluation of robotically-assisted surgery

Conclusions

- CDRH is committed to expanding Sentinel to include devices (per FDASIA 2012)
- Devices present unique challenges for postmarket surveillance
- Incorporation of UDIs into EHI is critical
- Registries will continue to be important data sources that, with further development, can complement Sentinel efforts