Closing Gaps in Our Postmarket Safety Net for Medical Devices: It's Everybody's Business!

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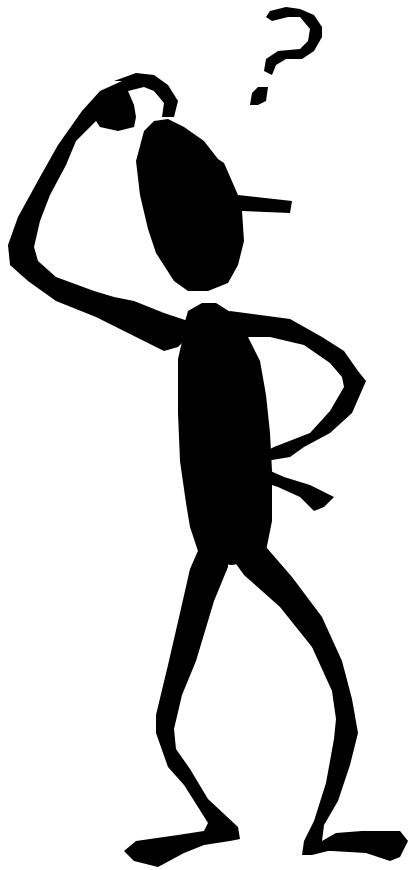
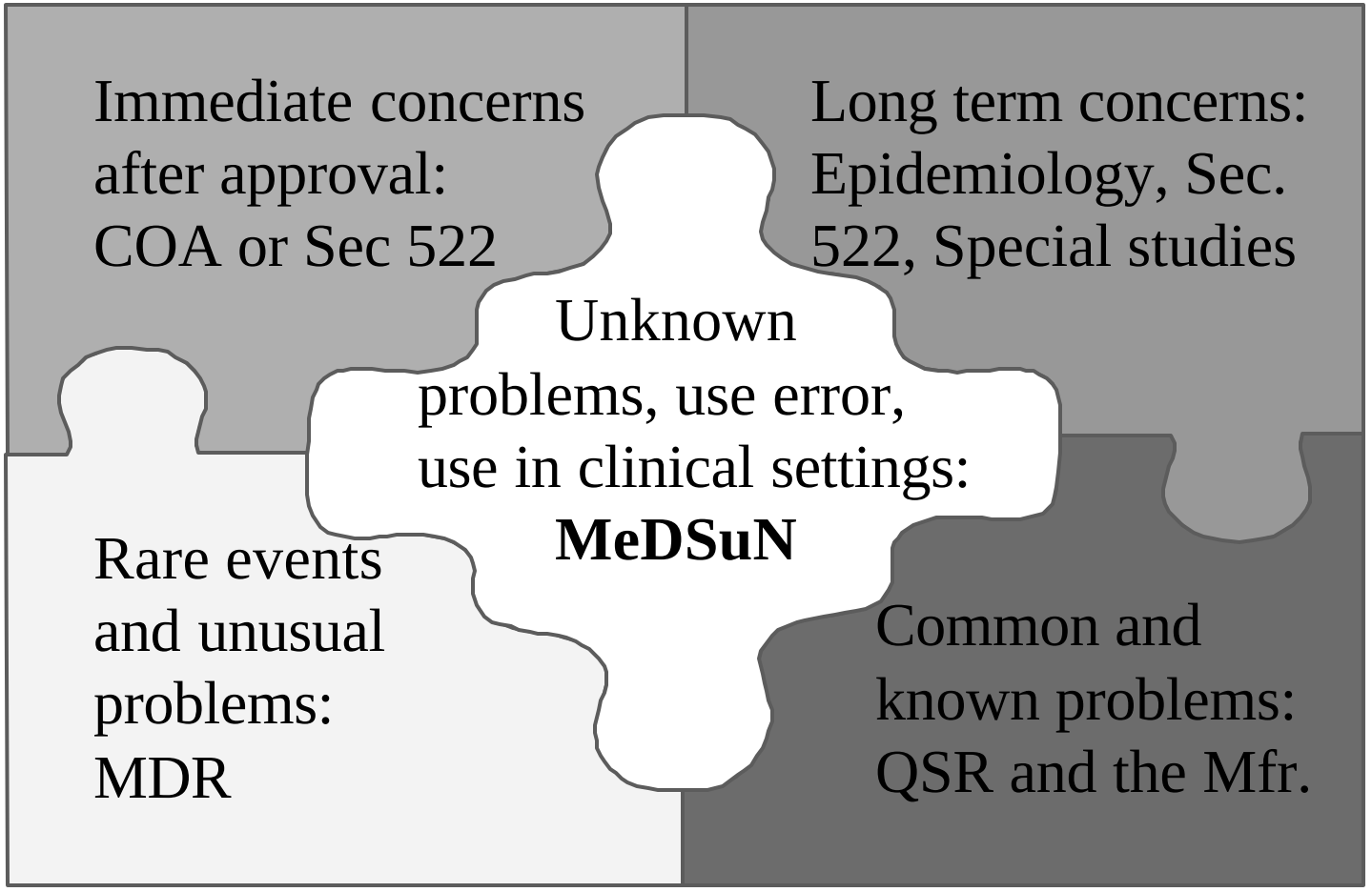
Questions of Interest in the Postmarket Period

- Long term safety
- After clinical trials, performance of device in community practice
- Change of user setting (e.g., hospital to home)
- Unusual pattern of adverse events not requiring product recall



Integrating the Pieces of the Postmarket Puzzle



Report Card for CDRH: The Sum total of PM

What can “go wrong” and how we find out

A rare but catastrophic event (e.g., explosion)	Medical Device Reporting (MDR) System
Common and known problems (e.g., infection)	Quality System Requirements (Mfr.)
Long term concern (e.g., failure over time)	***Epidemiologic studies, 522/PMS, Registries***
Immediate concern after approval	***Condition of Approval, 522/PMS***
Use error; use in clinical settings	***Medical product Surveil-lance Network (MedSuN)***

Holes in the Safety Net

- **MDR may not be able to detect increases in rates of known events; heart valves and perivalvular leak**
- **Specific disincentives to reporting, e.g., use error and bed rail entrapment**
- **MDR not a good mechanism for certain product classes, e.g., IVDs**
- **New technology and the learning curve, e.g., AAA Stent Grafts**

The Fundamental Problem?

For many devices, the lack of systematic data in the postmarket period hampers reasonable, science-based decision-making

Fixing the Holes in the Net

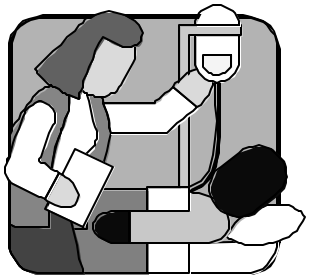
- **Medical Product Surveillance Network (MedSuN)**
- **Global Harmonization Task Force: SG2**
- **Postmarket Surveillance Authorities (Section 522; Condition of Approval)**
- **Registries; implant retrieval**

Medical Product Surveillance Network (MedSuN)

What:sample of medical facilities specifically trained in device reporting. Includes “potential for harm” reports.

Objectives: improved decision making about device problems; improved signal detection; improved patient safety.

Impact: better understanding of device problems such as human factors, new devices and clinical circumstances surrounding use.



Postmarket Study Authorities: Postmarket Surveillance (Section 522) and Postapproval (PMA)

- Two types of regulatory mechanisms
- Provide FDA the opportunity to ask key surveillance questions of “high risk” devices or where failure may cause death or serious injury
- Wide variety of surveillance approaches acceptable: think least burdensome but answer the key surveillance question

Attacking Postmarket Problems

- CDRH will: identify, prioritize, and communicate about postmarket device problems; even those not being addressed
- Focus on device type, not manufacturer-specific problems
- The focus is risk-reduction
- Registries may provide surveillance data
- Partnerships needed: FDA not always in lead

Registries and Possible Carrots from FDA's Perspective

- New product information
- Source of data for postapproval or postmarket surveillance studies
- Broader analysis of adverse events
- Regulatory requirements such as device tracking
- As potential sources for historical comparator data: from FDA's least burdensome guidance
- Pre/postmarket balance - expedite time to market w/ **reliable** postmarket data

Vision for the Future

Focus on total product lifecycle (feedback to premarket)

Developing a new system of reporting for a selected sample of well-trained and motivated hospitals; electronically based

Develop a prioritized and public list of device postmarket problems: focus on risk mitigation

Begin to issue postmarket surveillance orders under 522

Expand access to different data sources, e.g., registries, for both premarket (least burdensome) and postmarket control