Patient Safety: Emerging Opportunities in the Health Care System

Challenges in Understanding Adverse Events with Medical Devices

Larry Kessler, Sc.D.

Office of Surveillance and Biometrics

Center for Devices and Radiological Health, FDA

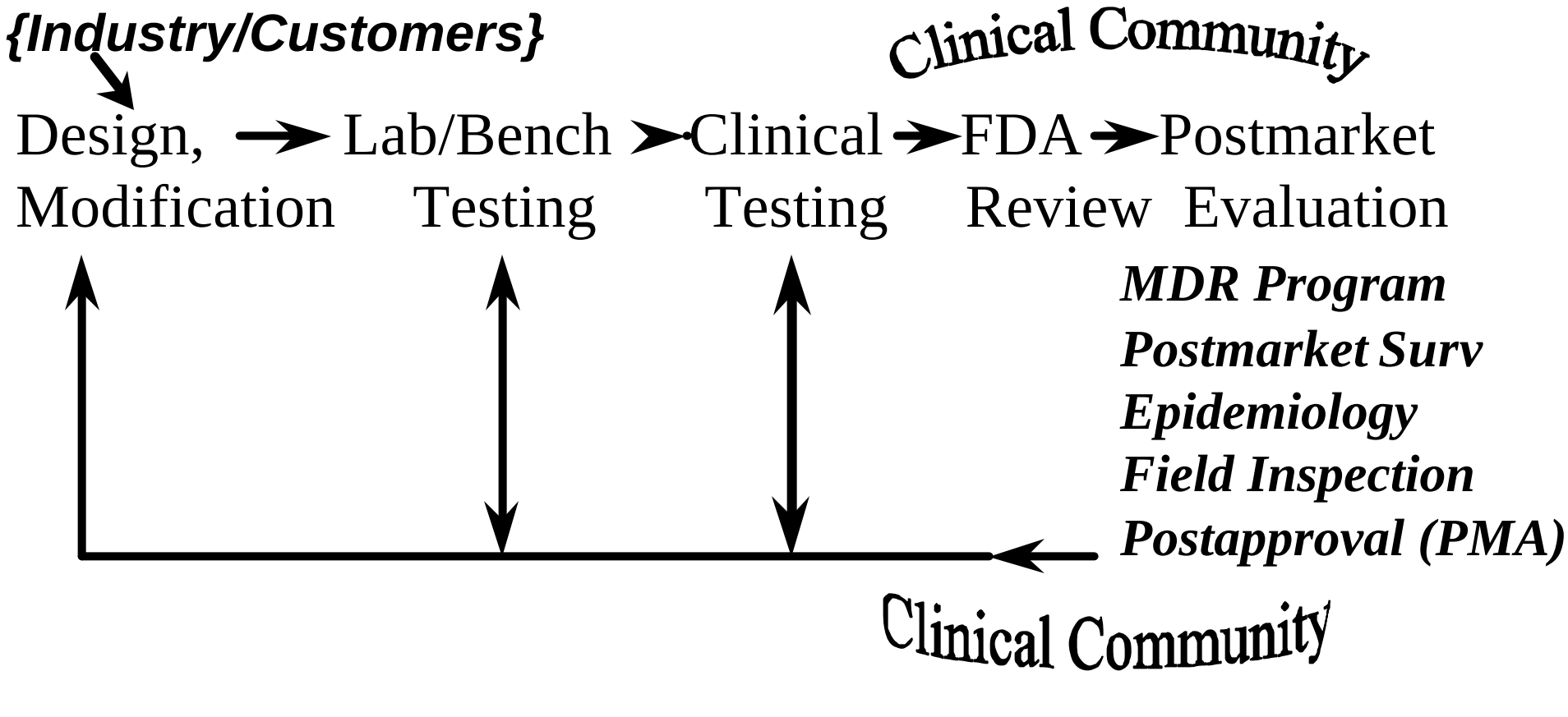
What you might not know...

- Medical devices are ubiquitous in the health care system (from IVD to PAC to ICD to MRI) and related to many “errors”
- Recognition of device errors or adverse events presents a series of challenges
- Under-recognition, under-reporting, and the “blame game” continue to act as obstacles
- We have a vision of the future: you can help

Two Examples of Device Issues

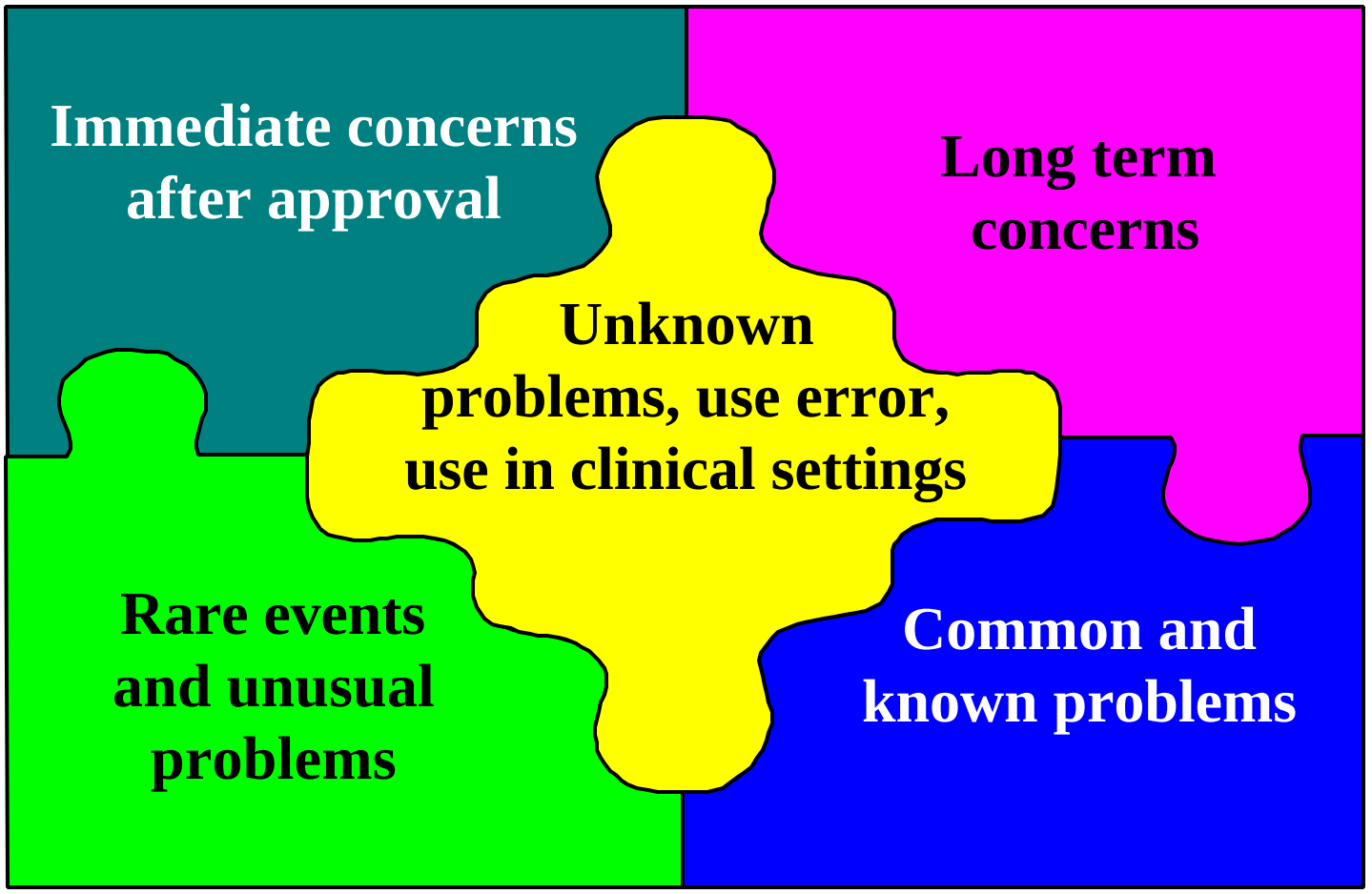
- Fetal Vacuum Extractors
  - Increase in reports of death and serious injury
  - Research literature indicating potential problems
  - FDA Public Health Advisory and ACOG response
- Hospital Bed Rails & the Vulnerable Patient
  - Motivated by concerns over hospital bed entrapment
  - Multi-agency and organization meeting April 1999
  - Seven task forces and follow up meeting Feb 2000

From Design to Obsolescence: Medical Devices and Center for Devices and Radiological Health, FDA



'Design' → Device evolution → 'Obsolescence'

Integrating the Pieces of the Postmarket Puzzle



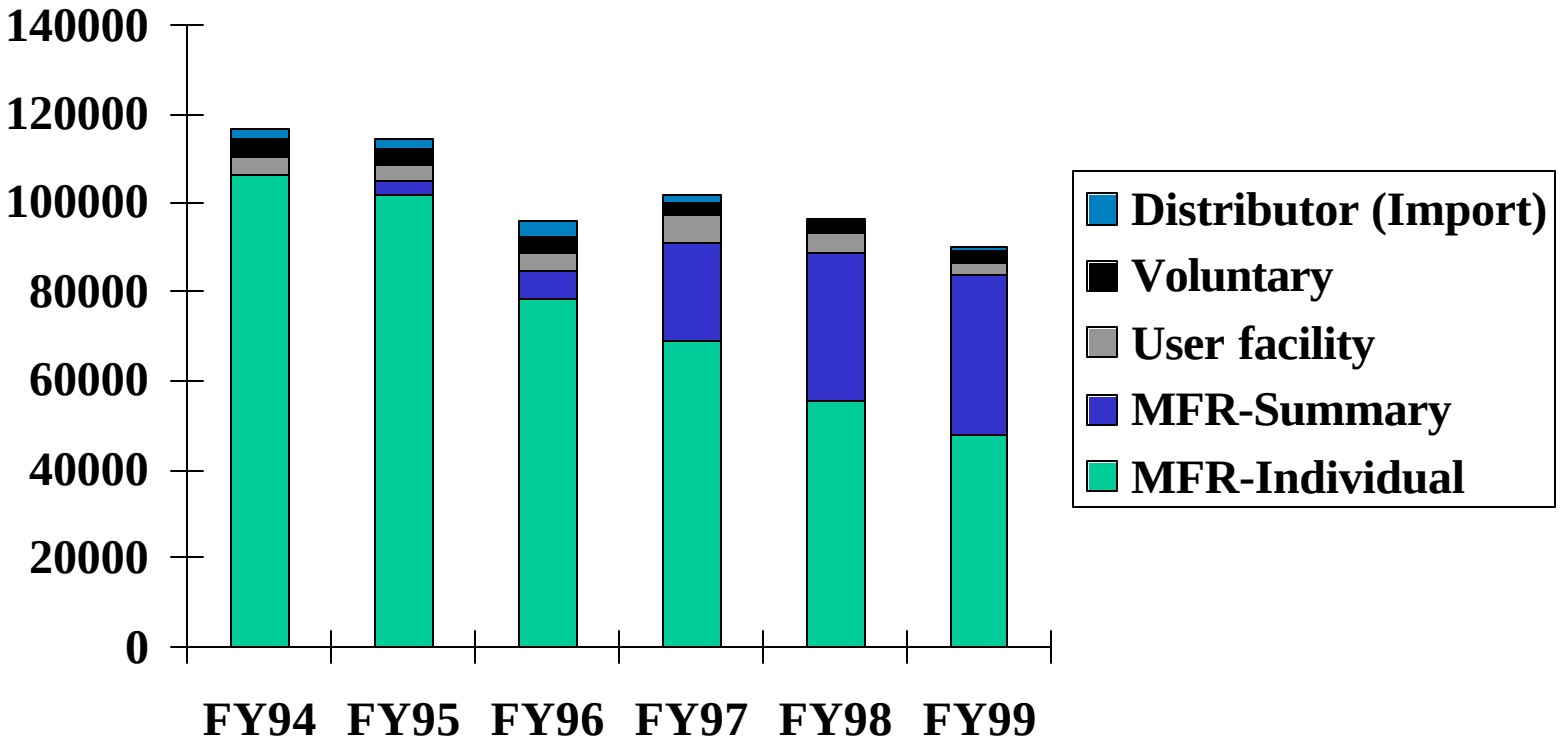
Example Device Problems Resulting in FDA Action

- **Immediate concerns: Use of TMR and injuries**
- **Long term: digital mammography Sensitivity, Specificity-work w/ACRIN**
- **Common and known: latex allergy; collaborative teleconference**
- **Use error: death assoc. with hemostasis devices - led to Public Health Advisory**
- **Rare and unusual:**
  - **Chlorhexidine impregnated catheters: hypersensitivity reactions - led to Public Health Notification**
  - **Infusion pump: explosion due to design failure - subsequent recall**
  - **Gamma camera: free swing of arm; potential death - International safety alert**

Unique Aspects of Device Events

- Lack of standard nomenclature for devices
- The concept of denominators, necessary to assess risk, under *development*
- Operator involvement and human factors issues inherent in virtually every event
- Complex multi-device situations are common leading to complex evaluation
- ***Information in reports often limited***

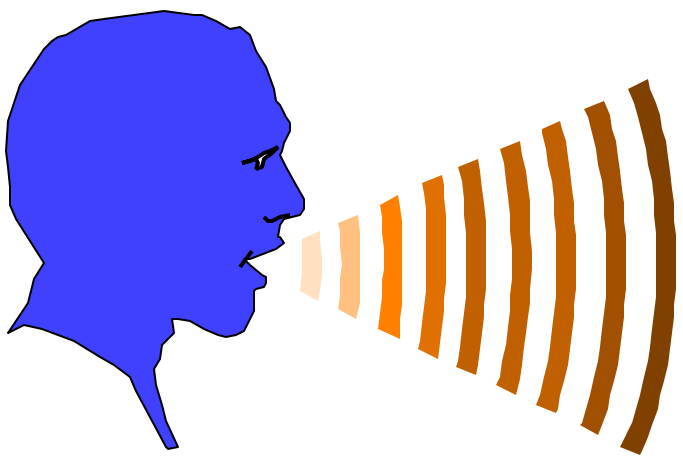
Medical Device Reporting Program: 1994-1999



Why We Need a New System

- FDA's current system is dominated by manufacturer reporting
- Most significant problems are discovered by the manufacturers well before FDA recognizes or needs to take action - there are, however, important exceptions
- User facility reporting has not lived up to expectations set in 1990

Sentinel Reporting
FDA's Pilot Program



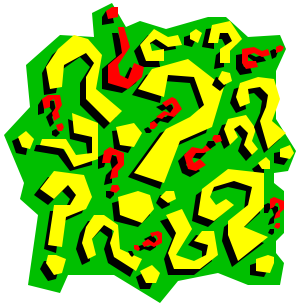
- "Sample" of user facilities committed to reporting
- Well educated and well monitored
- Regular feedback on performance or device information

Reporting Barriers

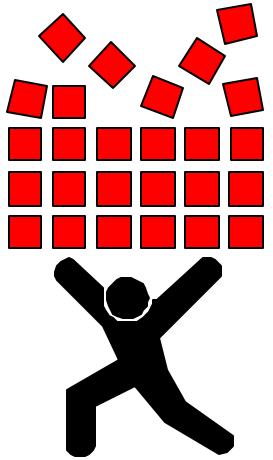
LIABILITY

Recognition

FEEDBACK



CONFUSION



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Vision for the Future

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

Expand system to include all medical products

Expand access to different data sources, e.g., registries

Improved knowledge of medical products in clinical settings

Focus of lifecycle of the product (feedback to premarket)

Prevention of error, improved patient safety