Medication Errors: An FDA Perspective

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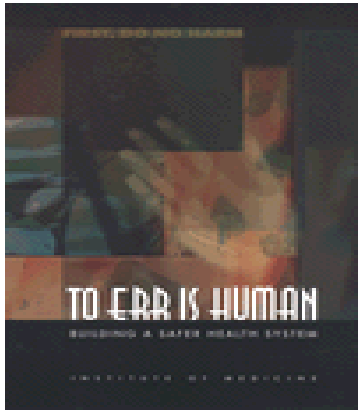
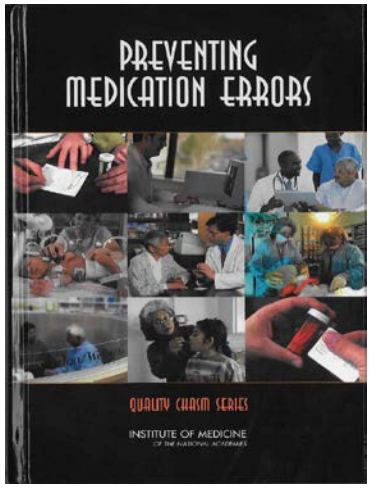
Background

- Historically, nomenclature and design issues with packaging and labeling of drug products were identified and remedied post-marketing
- Generally, the issues were resolved after medication errors had reached and harmed patients
- Proactive and preventative approach today

Exposing the Problem

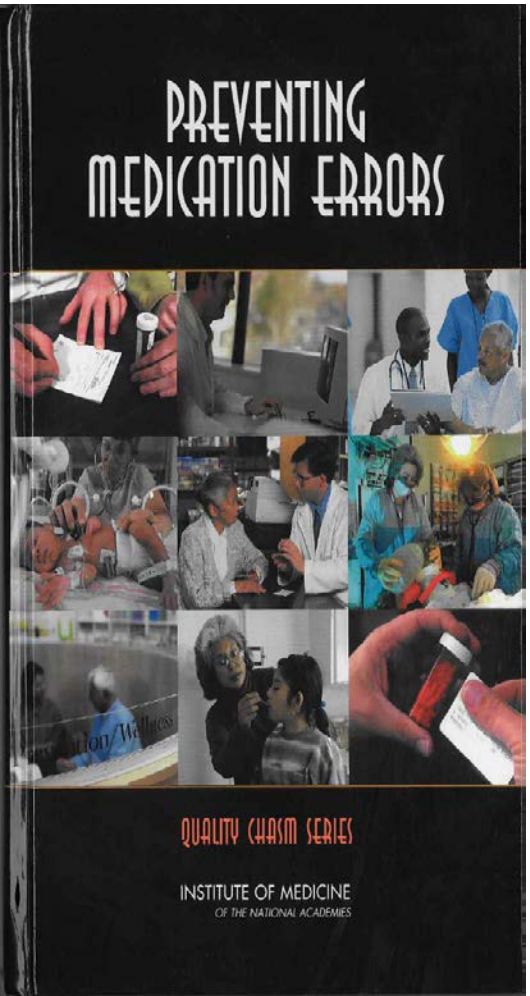


- December **1999** IOM report
  - 48,000 to 98,000 people die yearly due to medical errors.
  - **7,000** of which are related to **Medication Errors**
  - Recommended FDA develop processes to evaluate proprietary names and labels/labeling to minimize medication error



- July **2006** IOM report
  - Major Problems with Naming Labeling and Packaging
  - Cause of 33% of medication errors, including 30% of fatalities

2006 IOM Recommendations



- Urged FDA to incorporate the principles of Human Factors analysis to address issues concerning information presentation in labeling and nomenclature.
- FDA require FMEA as part of the design and assessment of labeling and packaging for all prescription drug products.

Efforts on Naming, Labeling and Packaging

- **Contents of Complete Submission**
  - Finalized February 2010
  - http://Details product information needed for proprietary name name review
  - Review clock starts with a Complete Submission
- **Good Naming, Labeling, and Packaging of Drugs/Biologics to Reduce Medication Errors**
  - Based on Post-marketing Experience
  - Public Meeting held June 2010
  - Draft End of FY 10
  - Guidance too large – Split into 3 guidance's
    - *Safety Considerations for Product Design to Minimize Medication Errors*
    - *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors*
    - *Best Practices in Developing Proprietary Names*
- **Best Test Practices for Proprietary Name Evaluation**
  - Concept Paper Basis for guidance
  - 2 years following accumulated data in Pilot Program
  - Public meeting to discuss results of pilot cancelled due to lack of participation
  - Combined into guidance #3 above

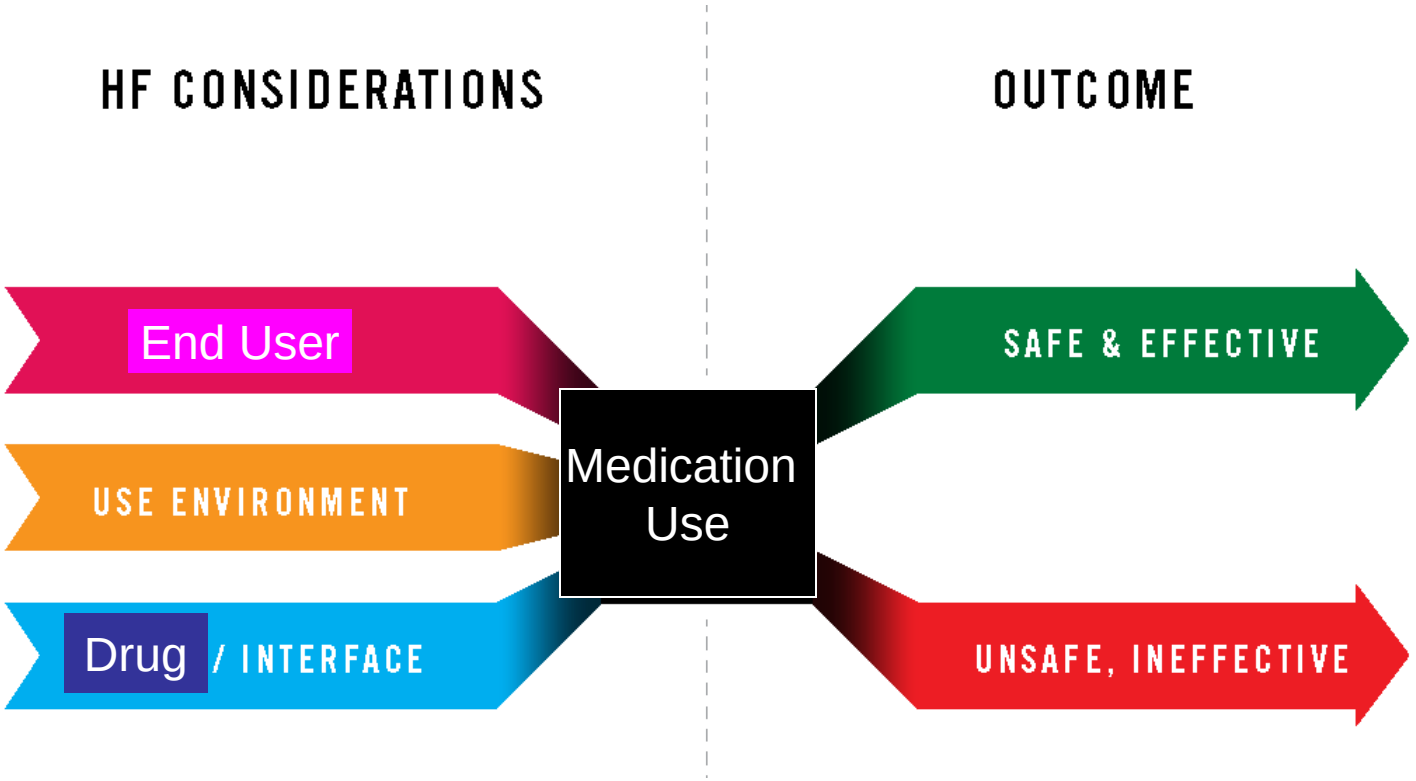
Guidance Program on Naming, Labeling and Packaging

- **Guidance 1: *Safety Considerations for Product Design to Minimize Medication Errors***
  - Issued December 13, 2012
  - Comment period closed February 2013
  - Provides sponsors with a set of principles for developing RX and OTC drug products using a systems approach to minimize medication errors relating to product design
  - Describes methods for proactive risk assessments of proposed product design and the container closure
  - Recommendations based on postmarketing lessons learned

- **Guidance 2: *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors***
  - Focuses on safety aspects of Rx container label and carton labeling design
  - Provides sponsors with a set of principles and recommendations for ensuring that critical elements of product labels and labeling are designed to promote safe use.
  - Recommendations based on postmarketing lessons learned

- **Guidance 3: *Best Practices in Developing Proprietary Names to Minimize Medication Errors***
  - Joint Guidance with CBER
  - Combination of Concept Paper **Plus** Postmarketing Lessons Learned
    - Final paper issued October 2008
    - (http://www.fda.gov/cder/guidance/8455%20FINALConcept%20Paper.pdf)
    - plus other recommendations for minimizing error based on postmarketing lessons learned

Human Factors of Medication Use



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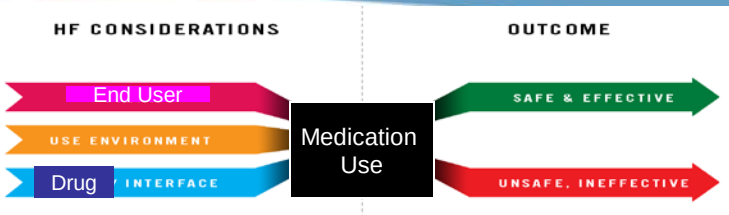
HF for Drug Products



- End user
  - Professional or non-professional
    - Patient, Caregiver, technician, or Healthcare Provider
    - May be all of above
  - Knowledge and Experience
  - Age and functional capabilities
  - Mental and Emotional Condition

- Environment(s) of use
  - Inpatient, outpatient, long term care, ambulance, home, etc.

- Interface for Drug Product
  - Container Closure and Actual Product Appearance
  - Product Design
  - Container label and Carton Labeling

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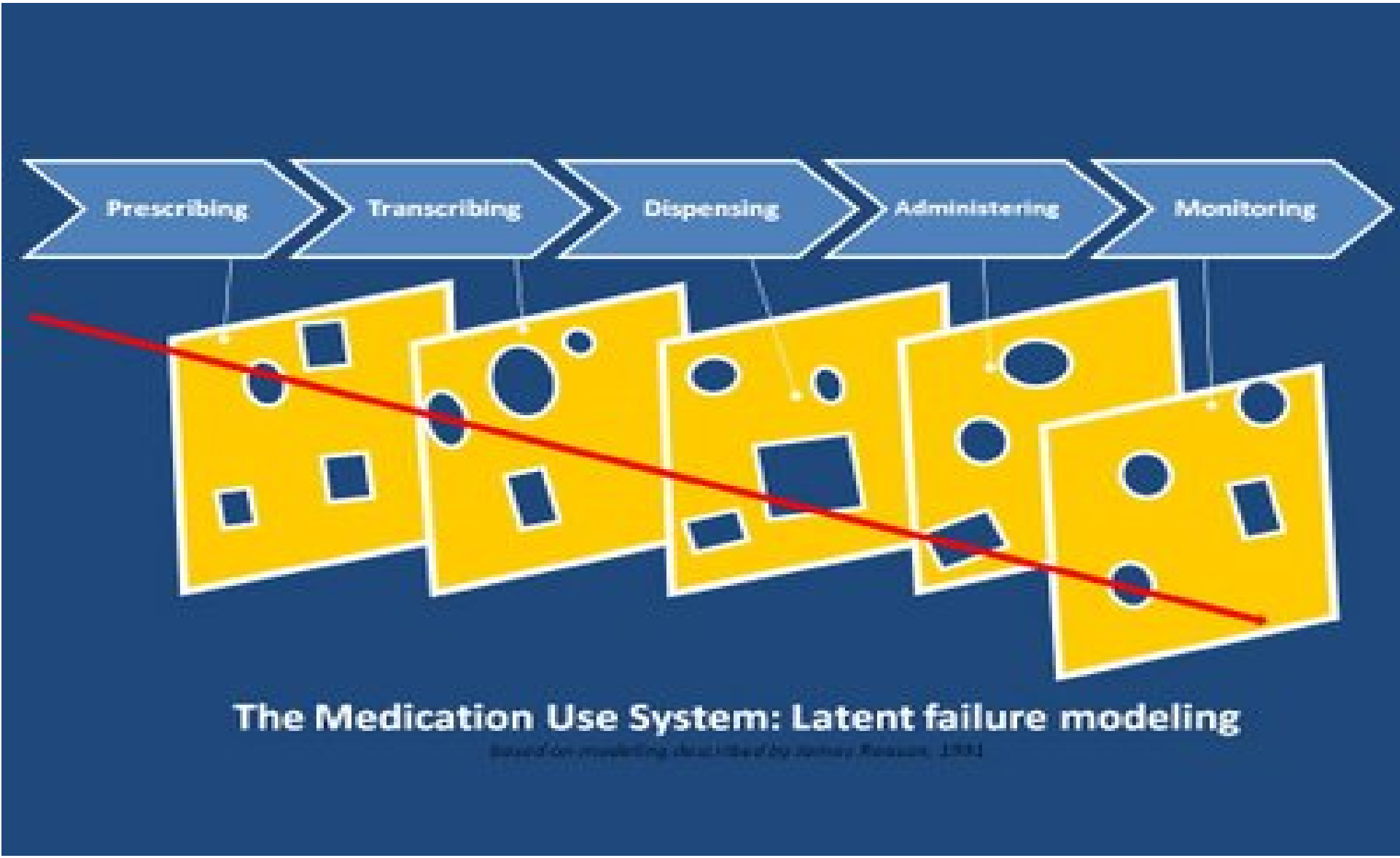

The Medication Use System: Latent failure modeling

http://florencedotcom.blogspot.com/2009/04/risk-points-across-medication-use.html

Questions