REM$ for Freelances

Brian Bass
Author, *The Accidental Medical Writer*
President, Bass Advertising & Marketing, Inc.
The (Brief) History of Drug Safety

Modern Age of Drug Regulation Begins
Risk Management Efforts Begin
Before the Era of Risk Management

- **Drug Importation Act (1848)**¹
  - Prevent adulteration of medicines
- **Pure Food & Drug Act (1906)**¹,²
  - Close loopholes in the Drug Importation Act
- **Food, Drug and Cosmetic Act (1938)**³
  - Close loopholes in the Pure Food & Drug Act
  - NDA to confirm safety
- **Kefauver/Harris Drug Amendments (1962)**⁵
  - Required proof of efficacy in addition to safety
  - IND introduced
In the Era of Risk Management

- Controlled Substances Act (1970)$^6$
  - Restricted prescribing, dispensing and patient access to certain drug classes
    - Opioid analgesics
    - Hypnotics
    - Tranquilizers
  - Increase accountability for drugs with higher potential for misuse, abuse and diversion
In the Era of Risk Management (continued)

• Patient Prescribing Information (1976)\(^6\)
  – Began with manufacturers of oral contraceptives
  – Required communication of risk and safety information to patients
  – Dawn of the PPI
In the Era of Risk Management (continued)

- Prescription Drug User Fee Act (PDUFA) (1992)\(^7,8\)
  - Authorized FDA to collect fees from manufacturers
  - Facilitated FDA staffing
    - Modernize FDA technology
    - Enhance drug approval process
    - Support post-marketing safety activities
In the Era of Risk Management (continued)

• FDA Modernization Act (FDAMA) (1997)\(^9\)
  – Reauthorized PDUFA
  – Encouraged collaboration between government and industry
  – Goals:
    • Increase patient access to experimental drugs and devices
    • Accelerate review of important new medications
In the Era of Risk Management (continued)

• Risk Minimization Action Plans (RiskMAPs) (2005)\textsuperscript{18}
  – First plan to make safety an ongoing process
    • Step 1: Access benefit-risk profile
    • Step 2: Develop and implement tools to minimize risks and preserve benefits
    • Step 3: Evaluate tool effectiveness and impact on risk-benefit profile
    • Step 4: Adjust as necessary
  – 3 Categories of tools
    • Level 1: targeted education and outreach
    • Level 2: Reminder systems
    • Level 3: Performance-linked access systems
In the Era of Risk Management (continued)

- FDA Amendments Act (FDAAA) (2007)
  - Paradigm shift
  - Transformed RiskMAPs into a mandatory and enforceable program
  - Ensure drug safety and ongoing pharmacovigilance throughout drug lifespan
  - Mandatory components:
    - Risk Evaluation and Mitigation Strategies (REMS)
    - Post-marketing studies
  - Compliance enforcement:
    - Civil monetary penalties
## REMS Components

<table>
<thead>
<tr>
<th>Level</th>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1     | Medication Guide | • Paper handout given to patients with Rx  
       |         | • Prevent serious AEs, aid patient decision-making,  
       |         | enhance adherence to safe use and handling  
       |         | • Address drug/class-specific issues  |
| 2     | Communication Plan | • Lay language of PI  
       |         | • Emphasize and instruct patients on side effects,  
       |         | precautions, dosage and administration  |
| 3     | Elements to Assure Safe Use (ETASU) | • Specialized HCP training, experience, certification  
       |         | • Certification of pharmacies, HCPs, HC settings  
       |         | • Restrictions on dispensing  
       |         | • Evidence/documentation of patient safe use  
       |         | • Patient monitoring  
       |         | • Patient registry  |
Opportunities for Medical Writers

- Development of REMS programs
- Implementation of REMS elements
  - Medication Guide
  - PPI
  - Communication Plan
  - Elements to Assure Safe Use
- Publication of post-marketing study results
References

References


Thank You