



Assessing Drug Safety

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Agenda

- Introduction/Overview - Seligman
- Pre-market assessment - Jenkins
 - Office of New Drugs
- Post-market assessment - Trontell
 - Office of Drug Safety
- Future Directions - Seligman



Goals

- How CDER is organized, staffed, “resourced” to assess safety
 - Clinical
 - Compliance & product quality
 - Risk communication
- How information flows within CDER
- Roles and responsibilities
- Key recent guidance documents



CDER Organization

- Key operational units
 - Office of New Drugs
 - Office of Pharmaceutical Sciences
 - Office of Pharmacoepidemiology & Statistical Science
 - Office of Compliance
 - Others (Office of Training and Communications, Regulatory Policy, etc.)





CDER Organization

- Office of New Drugs
 - 17 review divisions, plus OTC Office
 - 700 staff
 - review function
 - investigational drug applications
 - new drug applications





CDER Organization

- Office of Pharmaceutical Science
 - Generic drugs
 - Chemistry
 - Biotechnology products
 - Office of Testing and Research
- 331 staff





CDER Organization

- Office of Pharmacoepidemiology & Statistical Science
- Post-marketing risk assessment
 - Office of Drug Safety
 - 109 staff
- Biostatistics





CDER Organization

- Office of Compliance
 - New drug/labeling compliance
 - Manufacturing/product quality
 - 117 staff





CDER Organization

- Others
 - Communication/training
 - Regulatory policy
 - Medical policy





Recent Accomplishments

- Risk Guidance Documents
 - “Premarketing Risk Assessment”
 - “Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment”
 - “Development and Use of Risk Minimization Action Plans”
- Best practices for industry



Recent Accomplishments

- Good Review Practices
 - “Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review”
 - Reviewer guidance





New Initiatives

- Drug Safety Oversight Board
- “Drug Watch”
 - previously discussed by Dr. Galson





Breadth of Safety Activities

- Drug safety involves more than watching for problems after a drug is approved
- Important areas where evaluation of drug safety occurs include:
 - Oversight of clinical trials
 - Evaluation of safety and efficacy of new therapies, and new or expanded uses for existing therapies
 - Regulation of manufacturing, distribution and promotional activities.
 - Prevention of medication errors through the evaluation of proposed proprietary names, labeling, and packaging
 - Development of proactive risk management strategies before (and after) approval



Future Directions

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■ ■ ■ Develop Science of Safety

- Scientific basis for risk assessment
 - mechanistic understanding of drug injury processes
 - physiologic, metabolic, genetic bases for AEs
 - who is at risk
 - individual basis, population variability
 - markers for drug-induced injury
 - assessment “circumstantial”

■ ■ ■ Develop Science of Safety

- Enhanced clinical assessment methods
 - pre- and post-market
 - improved trial design
 - enrichment, adaptive designs
 - better utilization of existing data
 - robust Phase IV program

■ ■ ■ Better Surveillance Tools

- Improving quality & quantity of data
 - easier, interactive case reporting
 - electronic, web-accessible/fillable
 - “active” surveillance
 - linkage of datasets
 - electronic medical record
 - public and private sector
 - population-based data
 - regular, robust program of observation studies
 - analytic tools (e.g., data mining)

■ ■ ■ Strengthening CDER

- Staffing for enlarging mandate
 - review and evaluation of risk minimization action plans
- Improve internal processes
 - work processes, roles/responsibilities
 - communication
 - information flow
 - tracking and accountability

■ ■ ■ Strengthening Partnerships

- Federal agencies
 - CMS, AHRQ, CDC, NIH, HRSA
- Academia
 - CERTs
- Healthcare institutions
 - payers, providers
- Sponsors
 - pre- and post-marketing responsibilities



Effective Communication

- Improve therapeutics
 - realizing benefits
 - minimizing risks
- Enhance patient safety
- Reduce medication errors
- Healthcare system issue



Questions

- Site visit??

