CDER's Office of Surveillance and Epidemiology

Gerald J. Dal Pan, MD, MHS
Director
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research - FDA

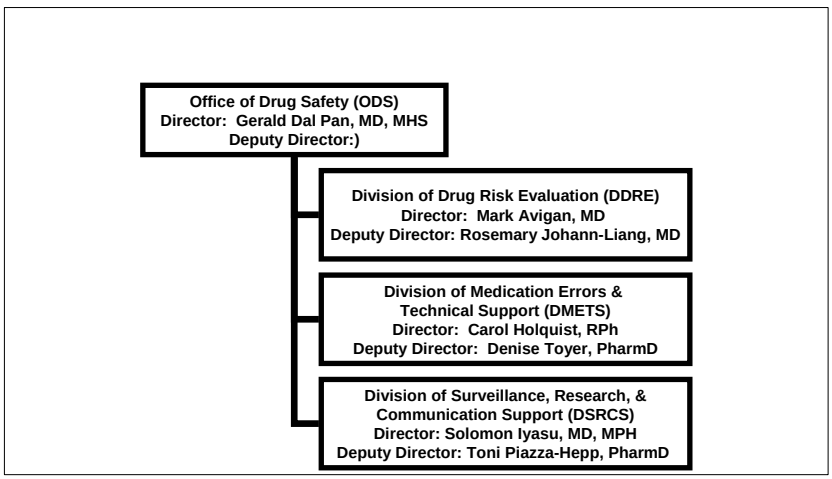
Office of Drug Safety's Mission

- **The Office of Drug Safety evaluates drug risks and promotes the safe use of drugs by the American people.**

Staff in ODS - currently ~130

- Safety Evaluators - Clinical Pharmacists
- Epidemiologists - MDs and PhDs
- Medical Officers
- Health Science Analysts
- Project Managers
- Contracts specialists
- AERS/ IT support
- Admin & Support Staff

Office of Surveillance and Epidemiology - Structure



Division of Drug Risk Evaluation (DDRE)

- Evaluates the **safety of marketed drugs**
  - Reviews adverse drug event reports with the Office of New Drugs
  - Recommends appropriate actions
- Estimates the **public health impact** of safety signals

DDRE, con't

- Performs **epidemiologic research** on drug safety issues
- Reviews **epidemiologic study protocols and results**
- Provides **recommendations** on risk management programs

Division of Medication Errors and Technical Support (DMETS)

- Evaluates & provides recommendations on **proprietary names** from a safety perspective to minimize medication errors
- Identifies error-prone aspects of **labels, labeling, & packaging** of drug products & provides recommendations to minimize user error

DMETS, con't

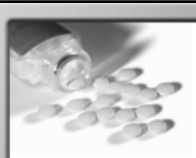
- Reviews postmarketing **medication error reports** & recommends appropriate actions to prevent further errors
- Provides **information technology support** to ODS (specialized database searches, websites, desktop support)

Division of Surveillance, Research, & Communication Support (DSRCS)

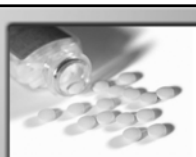
- Reviews **Medication Guides** & patient labeling
- Consults on **drug utilization databases** such as IMS Health, Caremark, Premier
- Oversees the **MedWatch** program
- Conduct pharmacoepidemiological analyses
- Reviews epidemiological studies

DSRCS, con't

- Handles data resources, risk communication, & outcomes/effectiveness research components of drug safety **risk management** programs
- Analyzes social science research on **risk communication** issues



New Drug Safety Initiatives



Drug Safety Initiatives

Announced on Feb 15, 2005
DHHS Secretary Mike Leavitt and
Acting FDA Commissioner Lester Crawford

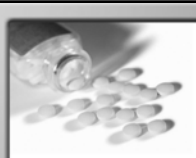
- Drug Safety Oversight Board
- Drug Watch Web Page
- Healthcare Professional Information Sheets
- Patient Information Sheets

Drug Safety Oversight Board - Responsibilities

- Management of important safety issues within CDER – e.g., Drug Watch postings
- Resolving disagreements over approaches to drug safety issues
- Assessing the need for Medication Guides
- Overseeing the development of CDER-wide drug safety policies

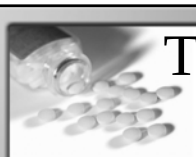
Drug Safety Oversight Board - Composition

- Members of FDA and medical experts from other HHS agencies, government departments appointed by FDA Commissioner
- Will consult with other medical experts and patient and consumer reps



Drug Watch Web Page

- Information included at direction of the Drug Safety Oversight Board on possible serious side effects or other safety risks of approved drugs
  - Potential to alter benefit/risk analysis
  - Affect patient selection or monitoring decisions
  - Can be avoided through measures taken to mitigate or prevent harm



The Adverse Event Reporting System - AERS

- Computerized database
- Contents: adverse drug experience reports from
  - Sponsors - mandatory reporting
  - Health care providers & consumers - voluntary reporting through MedWatch
  - Also medication error reports through MedWatch, USP, ISMP

Electronic Submissions (E-subs)

- Now accepting
  - Electronic submission of Expedited and Periodic ICSRs and attachments
  - E-sub of Descriptive Portion of Periodic Adverse Drug Experience Reports
- http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm
- www.fda.gov/cder/aerssub
- E-mail: aersesub@cder.fda.gov

Supplements to AERS

Data Resource Procurements
Cooperative Agreements
CERTS
Additional Resources

New Database Acquisitions

- Four organizations with linked pharmacy-medical claims databases
- Contracts signed September 2005
- Allows for collaborations between ODS epidemiologists and experts at these organizations
- Four organizations:
  - HMO Research Network/Harvard Pilgrim Health
  - Kaiser Family Foundation
  - Vanderbilt University
  - Ingenix (i3Drug Safety)

New Database Acquisitions

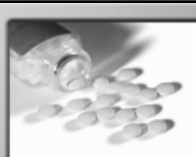
- Four organizations:
  - Harvard Pilgrim Health/HMO Research Network
    - Eight geographically diverse health plans with 3.2 million members
    - Electronic medical records available for 6 of 8 sites
  - Kaiser Family Foundation
    - 6.1 current members in northern and southern California
    - Fully integrated databases, linked to vital statistics and cancer registries
    - Unique formulary limited to selected drugs and indications
  - Vanderbilt University
    - Two state Medicaid populations (Tennessee and Washington)
    - 2.2 millions members, some at high medical risk (eg, the poor, nursing home residents)
  - Ingenix
    - Geographically diverse insured population of 12 million members
    - Some laboratory data also available

Centers for Medicare and Medicaid (CMS) Interactions

- ODS epidemiogists are working with CMS and AHRQ staff to understand better the nature of CMS data
- Current efforts focused on using Part B data for a pilot drug safety study
- Still in learning/exploratory stages

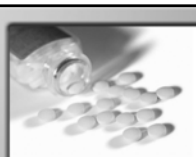
Active Surveillance

- Request for Information issued April 2005
- Responses received June 2005
- Responses currently under review
- Agency will decide on next steps



Other Developments

- White Oak
  - ODS moved to White Oak in later September 2003
  - All ODS offices on 3rd and 4th floors of the D wing
  - Allows for close collaboration within ODS and with the Office of New Drugs
- Process Improvement Teams
  - Office of New Drugs Process Improvement Team
  - Office of Drug Safety Consult Improvement Team

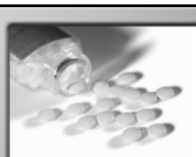


Drug Safety and Risk Management (DSaRM) Advisory Committee

- Established as full Adv Comm May 2002; as subcommittee Dec 2001
- To advise FDA on general and product-specific safety issues
- Independent opinions and recommendations from outside experts

DSaRM

- Member expertise:
  - Drug safety
  - Risk/benefit analysis
  - Risk perception, communication, and management
  - Ethics
  - Pharmacoepidemiology
  - Clinical pharmacology
  - Clinical research
  - Medication errors



DSaRM Use

- As full Advisory Committee
  - Meet alone
  - Meet with other full Advisory Committees
- One or more DSaRM members augments other Advisory Committees

Prescription Drug User Fee Amendments of 2002 (PDUFA III)

- Why? ... expediting the drug development process and the process for the review of human drug applications as set forth in the goals ...
- Effective Oct 1, 2002 to Oct 1, 2007
- http://www.fda.gov/cder/pdufa/

PDUFA Reauthorization Performance Goals and Procedures

- VIII. Pre- and Peri-NDA/BLA Risk Management Plan Activities
  - a. Submission and Review of pre-NDA/BLA Meeting Packages
  - b. Pre-NDA/BLA Meeting with Industry
  - c. Review of NDA/BLA
  - d. Peri-Approval Submission of Observational Study Reports and Periodic Safety Update Reports (PSURs)
  - e. Guidance Document Development

Risk Management Plan Review by OND and ODS

- From Oct 1, 2002 – Dec 31, 2004:
- Includes PDUFA and non-PDUFA
- Risk Management Plans reviewed - 62
  - Orig NMEs -8
- Pre-NDA meetings = 61

Future Directions for ODS

- New responsibilities under the Prescription Drug User Fee Act - Risk Management Plan Activities
- Research, development, and evaluation of tools for the safer use of drug products
- FDA initiatives on Drug Safety