Office of Drug Safety: Update

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IOM Study

- Planning Committee
  - Co-chairs:
    - Dr. David Blumenthal
    - Ms. Sheila Burke
  - Members' backgrounds are diverse
    - Medicine, health policy, public administration, nursing, law, bioethics, biostatistics, epidemiology, etc.

IOM Study (Cont'd)

○ Study Goals

- Examine the FDA's current role and the role of others (e.g., sponsors, health professionals, hospitals, patients, other public agencies) in ensuring drug safety as part of the U.S. health care delivery system;

IOM Study (Cont'd)

- ○ Study Goals (Cont'd)
  - Identify strengths, weaknesses and limitations of the current system;
  - Make recommendations in the areas of organization, legislation, regulation, and resources to improve risk assessment, surveillance and the safe use of drugs.

IOM Study (Cont'd)

○ Planning Meetings scheduled June, July, and October 2005

○ For more information: http://www.iom.edu/project.asp?id=26341

Differing Professional Opinion (DPO)

- MaPP 4151.2 "Documenting Differing Professional Opinions and Dispute Resolution—Pilot Program"
  - Describes how CDER staff may express differing professional opinions regarding regulatory matters/policy decisions

DPO (Cont'd)

- Provisions
  - Short time frames
  - Review of the DPO by qualified staff not directly involved in original decision
  - Evaluation of pilot program after one year for "value added"
- Procedure has not yet been used (MaPP was effective in November 2004)

Search: Office of Drug Safety Director

- Consistently difficult to attract and retain ODS Director
- FDA has partnered with OPM to conduct a more wide-ranging search
- Thorough analysis of position
  - Occupational studies
  - Government-wide leadership models
  - Focus groups

Search: Office of Drug Safety Director (Cont'd)

○ Goals
- Vacancy announcement:
  ○ Posted June 27, 2005
  ○ Open for 30 days
  ○ http://jobsearch.usajobs.opm.gov/a9fda.asp
    - Search on Director Drug Safety
- Selection: Late summer 2005

Drug Safety/Risk Management Consultations

○ FDA will conduct workshops and Advisory Committee meetings to discuss complex drug safety and risk management issues.

- May include emerging concerns for products that are investigational or already marketed. (e.g, whether a particular safety concern alters the risk to benefit balance of a drug; whether FDA should request a sponsor to conduct a particular type of study to further address an issue)

- These consultations will include experts from FDA, other federal agencies, academia, the pharmaceutical industry and the healthcare community

May 18-19, 2005 DSaRM AC Meeting

○ Purpose
  ● Explore issues related to FDA's risk assessment program for marketed drugs
    ○ Advantages, disadvantages of current system
    ○ Ways to improve current system
○ Outcomes
  ● Current passive system good for detecting rare, serious events with short latency periods
  ● Develop external relationships/alliances
  ● Need for adequate funding
  ● Need for additional research

Drug Safety/Risk Management Consultations (Cont'd)

- ○ Overall calendar of advisory committee meetings:
  - ● http://www.fda.gov/oc/advisory/accalendar/2005/default.htm
- ○ Tentative dates for Drug Safety and Risk Management (DSaRM) advisory committee meetings
  - ● October 26 and 27, 2005
  - ● December 8 and 9, 2005

Risk Management Guidances

Published March 24, 2005 at
http://www.fda.gov/cder/guidance

- /5766dft.pdf RiskMAPs
- /5765dft.pdf Premarketing
- /5767dft.pdf Pharmacovigilance

General Points about Guidances

- Two rounds of commentary valuable
  - Concept paper and draft guidance
- Framework, nomenclature will aid FDA and Industry discussions
  - Common terminology
  - Recommendations for when, how, what of discussions and submissions

Toolkit Strengthening

○ FDA has several tools available to address postmarketing safety concerns

- AE reporting
  - ○ Cornerstone of FDA's postmarketing surveillance tools
- Drug utilization databases
- US claims-based health encounter data (indirect access)

Toolkit Strengthening (Cont'd)

- Voluntary AE reporting
  - Provides limited information
  - Suffer from underreporting, attribution problems, reporting biases, and a lack of denominator information
- Goal: Strengthen and complement existing program, be proactive/purposeful
- Several gaps identified
  - Longitudinal electronic medical record data→ Contract to access GPRD awarded September 27, 2004
  - Active surveillance data

Active Surveillance

- Current effort to develop/work with active surveillance systems
  - National Electronic Injury Surveillance System (NEISS)
  - Drug Abuse Warning Network (DAWN)
- FDA issued a Request for Information (RFI) on existing US active surveillance systems
  - RFI issued April 18, 2005, responses due June 10, 2005
  - Reviewing responses and will determine next steps

Epidemiologic Data

○ FDA previously had indirect access to US claims-based health encounter data for epidemiologic studies via a Cooperative Agreement (i.e., grant) program

○ Currently in the process renewing access to these data via a Request for Proposals (RFP)

- RFP issued May 24, 2005; responses due July 5, 2005

- Will allow FDA more flexibility and access to wider range of data resources

Drug Safety Oversight Board

○ What is it?

- A group of government scientists, both internal and external to FDA and CDER, whose role is to advise the Center Director on matters related to
  - ○ Internal dispute resolution
  - ○ Internal standard setting
  - ○ Drugs that should be placed on the proposed Drug Watch page

- Most logistical details still being worked out!

Proposed Drug Watch Page

○ What is it?

- An Internet web page through which FDA is proposing to communicate "emerging" drug safety information to
  ○ Consumers
  ○ Health care professionals
- Communication will occur via posted Patient or Healthcare Professional Information Sheets
- Most logistical details still being worked out!

For More Information

- Information about the Drug Safety Oversight Board and the Proposed Drug watch page: http://www.fda.gov/cder/drugSafety.htm
- Draft "Drug Watch" Guidance: http://www.fda.gov/cder/guidance/6657dft.pdf
  - We welcome your comments!
  - Docket 2005D-0062

Conclusions

○ Detecting, assessing, managing, communicating the risks and benefits of drugs is complex and demanding

○ Number of initiatives, planned and ongoing, aimed at improving post-marketing risk assessment