FDA Center for Drug Evaluation and Research

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November 6, 2006

FDA Request to IOM

- Why did we request the Future of Drug Safety Study?
  - 2004 FDA initiative to strengthen and improve the management of drug safety issues

FDA Request to IOM

- What did we ask IOM to do?
  - Examine roles of FDA
  - Examine ongoing safety evaluation efforts
  - Evaluate existing tools, organization, and operations and authorities
  - Make recommendations in the areas of organization, legislation, regulation, and resources to improve risk assessment, surveillance, and safe use of drugs

FDA Perspective

- What process improvements in drug safety occurred during the IOM study?
  - Restructure
    - Increase management focus
    - Increase resources and staffing
    - Initiated process improvement projects

FDA Perspective

- What process improvements in drug safety occurred during the IOM study?
  - Restructure
  - Physician and patient information
    - Newly designed prescription drug labeling
      - Helps manage the risks of medication
      - Reduce medical errors
    - Public Health Notices
      - Health Care Practitioner and Patient information sheets

FDA Perspective

- What process improvements in drug safety occurred during the IOM study?
  - Restructure
  - Physician and patient information
  - Electronic drug label
    - New rule mandated more organized, informative labels
    - DailyMed web site provides access to current drug information

FDA Perspective

- What process improvements in drug safety occurred during the IOM study?
  - Restructure
  - Physician and patient information
  - Electronic drug label
  - Drug safety oversight board
    - Provides oversight and advice to FDA leadership on important drug safety issues

FDA Perspective

- What process improvements in drug safety occurred during the IOM study?
  - Restructure
  - Physician and patient information
  - Electronic drug label
  - Drug safety oversight board
  - Adverse event reporting system
    - Planning a replacement web-accessible computer system that will include signal detection and tracking tools
    - Developing a standard AE reporting form for all centers and for on-line submission

FDA

FDA Perspective on IOM Findings and Recommendations

FDA Perspective

- IOM report provides a significant opportunity to reexamine our approach to drug safety
- Renewed incentive to address tools, resources, and approaches to improve drug safety
- Identified vulnerabilities in the drug safety system
  - Chronic under funding
  - Organizational problems
  - Unclear regulatory authority and insufficiently flexible regulatory tools
  - Inadequate quantity and quality of post-approval data

FDA Perspective

- Five FDA drug safety working groups
  - Randall Lutter, PhD, Associate Commissioner for Policy and Planning provides oversight
  - December 15th goal
  - FDA cross-center effort to evaluate and consider for implementation IOM's proposed near-term improvements and longer-term proposals
  - Groups to identify and develop specific proposals

FDA Perspective

- Five FDA drug safety working groups
  - Regulatory authorities for drug safety
  - Science of safety
  - Communicating about safety
  - Resources for the drug safety system
  - Culture of safety

FDA Perspective

- IOM report provides a significant opportunity to examine CDER structure and organization
  - Support cultural change
  - Incorporate safety goals into PDUFA goals
  - Integrate postmarketing safety staff into drug review process and share post approval authority with drug review staff
  - Incorporate lifecycle approach to risk/benefit
  - Team approach to assessing safety and efficacy

FDA Perspective

- IOM report provides a significant opportunity to examine regulatory authority challenges
  - Clarification of agency enforcement authority
    - Labeling change negotiation
    - Post-approval studies (Phase IV)
  - New enforcement authority

FDA Perspective

- IOM report provides a significant opportunity to improve communication about safety
  - Public perceives all approved drugs as safe
    - All drugs have risks and benefits
    - Newly approved drugs have limited safety data

FDA Perspective

- IOM report provides a significant opportunity to address resource issues
  - Analyze and develop estimates to support improvements in drug safety and efficacy activities over a product's lifecycle related to prospective increase in both funds and personnel for FDA

FDA Perspective

- IOM report provides a significant opportunity to address the science of drug safety
  - Limited scientific capabilities and resources in epidemiology and informatics
  - Limited role for advisory committees, and lack of epidemiology expertise on committees
  - More public disclosure of drug information
  - Improved signal detection
  - Testing of safety hypotheses

FDA Perspective

- Questions??

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