Innovative Uses of Electronic Databases for Enhanced Post-Market Safety

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Key Questions for Drug Safety Initiatives

- Will the proposed steps have the greatest impact on reducing the likelihood of a recurrence of Vioxx- or SSRI-type events?
  - Determine potential risks, areas for heightened surveillance to improve benefit-risk assessments
  - Identify safety signals, and affected patients, quickly and reliably in post-market setting
  - Monitor patterns of drug use
  - Target needed postmarket clinical studies, in cases where safety signal is real but unclear whether drug caused it
- Will they do so without unnecessary costs?

Current System and Proposed Safety Changes

- Existing Initiatives: AERS and Administrative Steps
  - AERS is improving, but most adverse events missed or not captured in timely, consistent manner
  - Limited data, inconsistencies delay and complicate detection of safety signals in postmarket setting
  - Steps toward broad population-based monitoring system
- Pending Legislation
  - Many beneficial steps but still primarily drug-by-drug, manufacturer-based system
  - Not routine and systematic collection and analysis of utilization and outcome data on populations
  - Supports additional use of electronic population databases, but current databases insufficient and not part of comprehensive infrastructure (HMO Research Network includes approximately 20 million lives; electronic data available on far larger population)

21st Century System for Post-Market Drug Risks

- **Better Data:** Mechanism for pooling of relevant data from private and public electronic databases on prescription use and outcomes
  - Private health plans, Medicare, VA/DoD
- **Systematic Strategy for Analysis:** Based on expert advisory guidance, FDA oversees systematic identification of priority questions and mechanisms for answering them
  - New drugs, including post-market evaluation of potential safety "signals" in areas of heightened concern and rare serious events
  - Unresolved safety questions with existing drugs
- **Public-Private Collaboration:** Independent, private research groups assist FDA in conducting analysis; methods and results available for public comment
- **Supplemental Clinical Studies:** Resources for post-market clinical studies can be focused more effectively on cases where safety signal detection is not sufficient to resolve whether drug causes elevated risk of adverse event

Enhanced Post-Market Infrastructure Is Feasible Now

- Electronic Private-Plan Databases and CERTs Network
- Electronic Medicare Data
  - A,B data already shared with FDA
  - Proposed regulation for Part D data use
- Potential for Medicaid Data
  - Some state programs already contributing data
- Well Over 100 Million Lives
  - Vioxx safety signal could have been observed in a few months of observation – rather than years
  - Can assess drug class effects as well as individual drug safety issues
- FDA New Drug Review Pilot and Sentinel Network Development
- Public and Private Support
  - Potential for significant private-sector assistance in developing data infrastructure
  - Significantly lower overall costs, in addition to better information, compared to drug-by-drug monitoring strategy

Post-Market Infrastructure: Some Further Issues

- Large, more consistent, more comprehensive, more timely population-based data
- Lower overall cost of postmarket monitoring by creating infrastructure for addressing key potential safety signals
- Better targeted and more timely post-market clinical studies
- Continued assurance patient confidentiality and appropriate use of data for key safety questions
- Need further development of statistical methods for observational data, to enhance value of data and guide further development of electronic data sources
- Provide progress and momentum toward more sophisticated health system based on interoperable electronic medical records
- Requires new and ongoing funding – but significantly less than drug-by-drug approach
- Necessary and feasible next step to establish science and culture of translational medicine with continuous quality improvement