Strategies for Establishing An Effective Long Term Post Marketing Surveillance Capacity

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How We Got Here - 1990s

- Drug recalls of the late 1990s (Trovan, Trogliazone, Cisapride) were based in part on inability to influence prescriber behavior
- Result has been to build a risk management framework - this works to a degree
- Solves problems on an ad-hoc basis, creating inefficiencies, costs, confusion
- It was a framework for dealing with the problems we knew about

How We Got Here - 2004

- SSRIs - persistent safety signal with no ability to effectively pool data and evaluate it - no class-effect trials

- Vioxx - suggestive data with no ability to adjudicate findings in a timely fashion and probe class-effect questions (NSAIDS vs Cox II Selective NSAIDS)

Where Things Stand

- Kennedy-Enzi
- Safe Drug Compounding Act
- Laboratory Test Improvement Act
- Pharmaceutical Market Access and Drug Safety Act
- Fair Prescription Drug Competition Act

Where Things Stand: Limitations of Spontaneous Reports

- Passive surveillance system
- Under-reporting exists
- Quality of the reports is variable/incomplete
- Duplicate reporting occurs
- Incidence rate cannot be determined
  - Numerator is uncertain
  - Denominator can only be projected

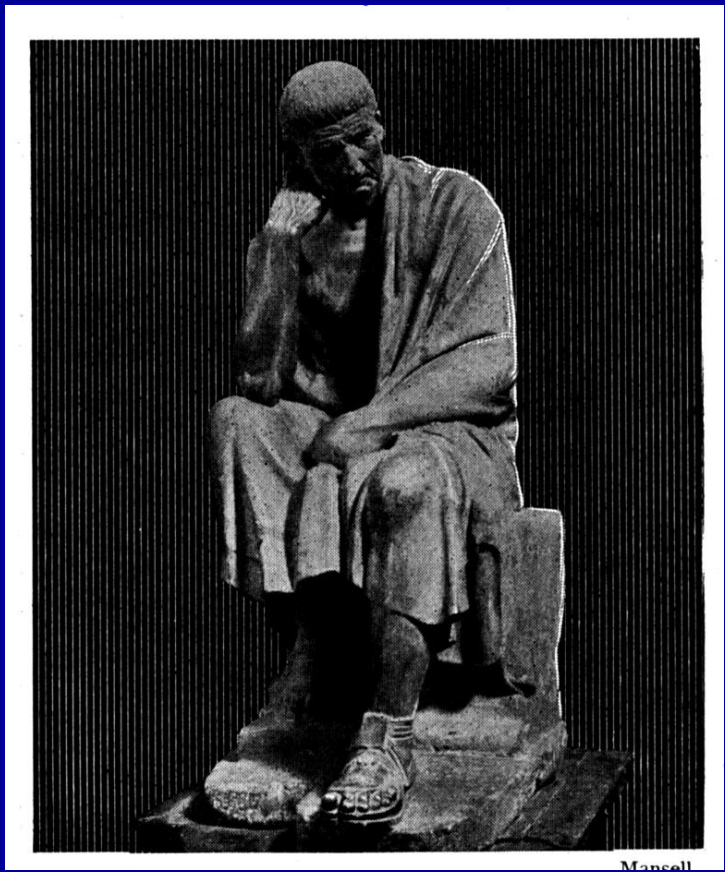
Where Things will End up

- FDAMA failed to produce expected improvements
- Backlash to confluence of recalls in 1990s failed to improve prescribing
- IOM Report didn’t address science

Where Things will End up

- Title 1 - focus on old ideas (RiskMaps)
- Authorities don’t address underlying shortcomings
- Ideas in Title 1 and IOM were resurrected from the 1990s

Good Ideas to Shore up FDA?



- Near real time or real time signal spotting (MedSun, CBI at MIT)
- Tools for adjudicating signals (Columbia University collaboration)
- Improved tools for risk communication

Major priorities for an enhanced post-marketing surveillance system?

Two Near Term Goals

- Active or near-real-time detection
- Better adjudication through academic partnerships like Columbia Presbyterian and access to funding for answering extraordinary drug safety questions

What are the key components of infrastructure required for an effective system?

- Access to clean data sets -- FDA Needs to be able to effectively pool data
- Ability to evaluate and refine data sets to meet public health goals (Columbia)
- Ultimately, FDA needs to invest in tools for data management, data evaluation, applications development to effectively manage separate streams of information

Which organizations should be involved in building and managing this system?

- FDA needs to partner with broader IT community to develop tools for sharing data (Sentinel Network)

- Final adjudication of data needs to reside with FDA which alone owns serious drug safety pronouncements - Payers cannot get into the business of being drug safety experts (signal to noise ratio)