Gaining the Public Trust

Ensuring Drug Safety, Efficacy, and Availability

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March 12, 2007

Overview

- General Public Expectations
- The Future of Drug Safety
- Identification of the Problem
- Solutions

Public Expectations

- Approved drugs are perfectly safe and effective
- FDA is responsible for protecting public from all problems
- Complete product information and potential interactions are known
- Side effects are understood and unlikely
- Lack of debate of patient needs

Declining Public Trust in FDA

- Culture & Media focused on negative
- Vioxx remains the primary safety example
- IOM report gained wide-spread media attention
- Continuous Congressional investigations and quick-fix legislation

Panel faults way FDA approves new drugs

The Washington Post

Report assails FDA on drug safety, says agency rife with squabbling

The New York Times

Eroding faith in the FDA; Restore funding, focus for strict drug-safety testing

Daytona Beach News Journal

Drug Safety Overhaul Is Urged

The LA Times

"…a dysfunctional Food and Drug Administration…" - AP

The agency needs cultural changes – Associate Press

The Future of Drug Safety:
Managing Expectations

- Enhancements can be made to the current system to improve drug safety, but must be handled with careful consideration
- Need improved methods to predict safety and efficacy for all drugs and combination therapies
- There is no instant or single method to ensure drug safety
- Beware of unintentional negative consequences to medical practice or innovation

Drug Safety Problems

- Over Burdened Agency
- Chronic Under Funding
- Public Outcry for Change
- PDUFA provides the “must-pass” vehicle for other FDA proposals
- Current legislative proposals will not prevent another “Vioxx”

What's at Stake?

- One-size-fits-all safety requirements for approval could restrict patient access to potentially life saving treatment
- Over-regulation that slows approval increases the cost of medical care, thereby decreasing access to medications because of their expense
- High regulatory hurdles discourage innovative product development
- Is there any net gain of making the system increasingly more regulated and complex?

DRUG SAFETY & DRUG EFFICACY
TWO SIDES OF THE SAME COIN

A Proposal for Improving Drug Safety, Ensuring New Drug Access, and Strengthening the FDA

a white paper
REPORT
2007

Academic clinicians and advocates convened to provide independent recommendations on drug safety

- Continually and simultaneously evaluate safety and efficacy
- Establish a systematic approach to post-market safety surveillance
- Improve current IT capabilities and increase personnel training
- Enhance existing infrastructure and engage in partnerships to improve post-market safety monitoring and evaluation
- Advance current scientific opportunities through the Critical Path Initiative

Focus on the Patient

- Millions are impacted by life-threatening illnesses. These are the people that need improved therapy options
- New technology is leading to less toxic and more targeted medicine
- While safety remains a high priority, excessive regulatory barriers can prevent patient access to life-improving treatments
- Patients deserve cutting edge treatments and need to know how to access them
- There is a spectrum of disease ranging from prevention to terminal illness that must be considered

Solutions

- Resources for FDA
- Routine analysis of population-based data sources
- Commitment to advancing science and technology
- Improved communication
- Public Education
- Managed Expectations

How “Safe” is Safe?

“An otherwise harmless drug can be dangerous if it does not produce its purported therapeutic effect.”

- Sen. Kefauver, 107 Cong. Rec. 5640 (1961)

“What do you expect from life – full coverage against all possible risks?”

- Raymond Chandler’s “*The Long Goodbye*”