

***SCIENCE AT FDA: CHALLENGES
AND OPPORTUNITIES***

PHYSICIAN'S PERSPECTIVE

**National Academy of Sciences
April 21, 2008**

**Robert C. Young MD, Chancellor
Fox Chase Cancer Center**



WHAT PHYSICIANS WANT FOR PATIENTS

t Safe and Effective Drugs and Biologicals

- Balanced for seriousness of illness
- Timely approval and better post-marketing surveillance
- Timely integration of lower cost generics and follow-on Biologics
- Safe pharmaceuticals imported into US - Heparin

t Safe Food Supply Free From Pathogens and Toxins

- 78% Reduction in food inspections in last 35 years
- Inspection of food manufacturers 1x/10 years

t Safe and Effective Medical Devices and Biomarkers

- Cost-effectiveness comparisons
- Better post-marketing surveillance

t Safe Food Additives, Color Additives and GRAS = GRAS

t And an FDA with the Manpower, Resources, Expertise To Keep Us Safe

CAN THE FDA ADDRESS THE PUBLIC AND PATIENT'S NEEDS?

t Safe and Effective Drugs and Biologicals

- PUDUFA funds have helped approval but distorted FDA funding and focus
- FDA ill-equipped to do post-marketing surveillance
 - Recent collaborations noteworthy

t Safe Food Supply

- IOM - FDA does not have capacity to ensure the safety of food
- 1991 Report documents same deficiencies

t Safe and Effective Medical Devices and Biomarkers

- Flawed products remain available while revised applications await FDA approval
- FDA does not regulate laboratory-developed tests (LDT's)
 - LDT's often influence drug selection or dosing

WHY CAN'T THE FDA DO IT'S JOB?

t Massive Accumulation of Unfunded Statutory Responsibilities

- 100 since 1988

t Inadequate IT Infrastructure

- CBER ≠ CDER; Road Salt = Table Salt

t PUDUFA Masks Shrinking Funds For Core Functions

- \$250M Lost from 2002-2005

t Lack of Personnel

- Lost 1311 Positions Since 1994

t Need Professional Development; Research Collaborations; Better Career Ladders

FDA NEEDS TO ADDRESS “NEW SCIENCE” OF 21ST CENTURY

- t Congress Must Address Funding, Manpower,
IT Needs of the FDA**
- t Collaborate Better and Eliminate “Center Silos”**
- t Create Position of Chief Scientific Officer in Addition
to Chief Medical Officer**
- t Create New Science Capability**
 - **Genetics, Systems Biology, Pharmacogenetics**
 - **Biomarkers, targeted therapies, prevention**
- t Fully Fund Critical Path Initiative**
- t Create Board of External Scientific Counselors**

FDA AND PUBLIC HEALTH

t Cannot Be Fixed With Existing Resources

t Many Excellent Reviews Have Identified Same Deficiencies For Decades

t Problem is Congress - Not the FDA